UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA *ex rel.* JOHN KING, *et al.*,	§	
Plaintiffs,	§	
v.	§	CIVIL ACTION H-06-2662
SOLVAY S.A., *et al.*,	§	
Defendants.	§	

ORDER

Pending before the court are (1) defendants Solvay America Inc. ("SAI") and Solvay North America LLC's ("SNA") motion to dismiss relators John King and Jane Doe's (collectively, "Relators") fourth amended complaint ("4AC") (Dkt. 121); and (2) defendant Abbott Products Inc.'s, which was formerly known as Solvay Pharmaceuticals Inc. ("SPI"), motion to dismiss Relators' 4AC (Dkt. 122). Having considered the motions and related documents, including the United States' statement of interest (Dkt. 130), as well as the applicable law, the court is of the opinion that SAI and SNA's motion to dismiss (Dkt. 121) should be GRANTED IN PART AND DENIED IN PART, and SPI's motion to dismiss (Dkt. 122) should be GRANTED IN PART AND DENIED IN PART.

I. BACKGROUND

This case is about a pharmaceutical manufacturer and its affiliates that allegedly made millions of dollars by marketing three drugs—Luvox, Aceon, and AndroGel—for conditions other than the conditions for which the drugs were approved by the Food and Drug Administration ("FDA") and by offering kickbacks to physicians who prescribed the drugs. Dkt. 114. Relators worked for SPI as district sales managers, and they were responsible for supervising sales

representatives who marketed AndroGel, Luvox, and Aceon (collectively, the "Drugs at Issue"). Dkt. 114 at 150; Dkt. 122-2 at 1. Relators claim that their employment was terminated after they questioned the ethics and legality of off-label promotions and kickbacks. Dkt. 114 at 150-57. Relators thereafter brought this *qui tam* action against Solvay SA, SAI, SPI, SNA, Solvay Pharmaceuticals SARL, and Abbott Products, Inc.,[1] on behalf of the federal government and the States of Illinois, California, Colorado, Florida, Tennessee, Texas, Delaware, Nevada, Louisiana, Hawaii, Georgia, Indiana, Michigan, Montana, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, Wisconsin, and Maryland, the Commonwealths of Massachusetts and Virginia, and the District of Columbia, asserting claims for violations of the federal False Claims Act ("FCA"), as well as various state versions of those statutes.[2] Dkt. 114 at 171-248. Relators also claim that Solvay conspired with physicians to promote off-label uses of the Drugs at Issue in violation of the FCA and to pay kickbacks in violation of the federal Anti-Kickback Statute ("AKS"). *Id.* at 169. Finally, Relators contend that Solvay retaliated against them in response to their questioning its marketing schemes by first criticizing Relators and eventually terminating their employment. *Id.* at 166.

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[1] The court will refer to the Solvay entities that remain in the lawsuit—SAI, SNA, and SPI—collectively as "Solvay."

[2] The federal government, the States of California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the District of Columbia, and the Commonwealths of Massachusetts and Virginia, have officially declined to intervene. *See* Dkt. 24 (Nevada) (sealed); Dkt. 25 (California) (sealed); Dkt. 44 (Florida) (sealed); Dkt. 45 (Texas) (sealed); Dkt. 52 (Delaware, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Virginia, Wisconsin, and the District of Columbia) (sealed); Dkt. 96 (Montana); Dkt. 97 (Georgia); Dkt. 143 (Colorado); Dkt. 144 (Maryland). Some of the state FCA claims were added when Relators amended their complaint.

A. Procedural History

On June 10, 2003, Relators filed their original complaint in the Eastern District of Pennsylvania. Dkt. 1. The Relators moved to transfer venue to the Southern District of Texas on June 26, 2006, and the court granted that motion on June 27, 2006. Dkt. 27 (Sealed). Relators filed their first amended complaint on July 15, 2008. Dkt. 38. They filed their second amended complaint on December 7, 2009. Dkt. 54. SAI and SNA filed a motion to dismiss the second amended complaint on March 19, 2010, and SPI filed a motion to dismiss the second amended complaint on the same day. Dkts. 94, 95. Relators moved to amend their complaint, and the court granted that motion and denied the motions to dismiss as moot. Dkts. 99, 102, 104. Relators filed their third amended complaint on September 15, 2010. Dkt. 111. The third amended complaint contains confidential information about physicians who prescribed the Drugs at Issue. Dkts. 112, 113. On September 30, 2010, Relators filed their fourth amended complaint, which is substantially similar to the third amended complaint except that the confidential information has been removed or altered to address the confidentiality concerns. *See* Dkt. 114.

On December 7, 2010, Abbott and SPI filed a motion to dismiss the 4AC in which they assert (1) the alleged violations of section 3729 of the FCA are insufficiently pled under Rules 8(a), 9(b), and 12(b)(6); (2) the alleged violation of section 3730(h) of the FCA is time-barred and fails to allege facts supporting each element of the cause of action; (3) the state *qui tam* claims in counts 5-33 are insufficient for the same reasons as the FCA claims and for additional state-specific reasons; and (4) count 34 requests "common fund relief" against states, which is not a cause of action. Dkt. 122-2.

On November 30, 2011, SAI and SNA filed a motion to dismiss the 4AC in which they argue that the 4AC (1) fails to allege with particularity the roles of SNA and SAI in the alleged misconduct; and (2) fails to plead any facts showing that SNA or SAI engaged in any misconduct or that they exhibited the total control and dominion of SPI that would be required for Relators to state a claim against SNA and SAI for the alleged misconduct of another corporate entity. Dkt. 121-1. SNA and SAI additionally move for dismissal of the claims against them for all of the reasons asserted in SPI's motion. *Id.* Both motions request prejudicial dismissal. Dkts. 121-1, 122-2.

B. Alleged Off-Label Promotion

Relators contend that Solvay inappropriately marketed the Drugs at Issue for off-label use by (1) encouraging its sales representatives to market the drugs to specifically targeted high Medicaid prescribers who Solvay deemed likely to heavily prescribe the drugs; (2) "shaping the science" through medical literature by paying influential doctors to research and write about the off-label uses that provided the most promise of profit; and (3) influencing physician speakers to promote the drugs off label. *Id.* at 95-107.

1. Luvox

Luvox, which is the trade name for fluvoxamine, was initially approved by the FDA in 1994 for the treatment of Obsessive Compulsive Disorder ("OCD"). *Id.* at 26-27. Luvox CR is an extended release version of Luvox. *Id.* at 30. In 2007, the FDA approved Luvox for the treatment of Social Anxiety Disorder in adults, and it approved Luvox CR for the treatment of both OCD and Social Anxiety Disorder in 2008. *Id.* at 30-31. Relators contend that Solvay marketed Luvox for use in treating depression, anxiety-related disorders, and other conditions of what Solvay called the

"OC Spectrum,"[3] such as stand alone anxiety disorder, Tourette's syndrome, anti-social personality disorder, schizo-obsessive disorder, sexual compulsions, and ADHD, even though Luvox was not approved for the treatment of these conditions. *Id.* at 31. Relators also contend that Solvay downplayed important risks associated with Luvox, including drug interactions, cardiovascular risks in older patients, and an increased risk of mania in children and adolescents.[4] *Id.* at 43-47. Relators claim that Luvox was a top-selling drug for defendants, with $6 million in Medicaid claims in Texas alone. Relators point to specific physicians in Texas who prescribed Luvox to patients for off-label use after sales representatives "pitched" these uses during sales calls. *Id.* at 50 & Exh. 18.

2. Aceon

Aceon, which is the trade name for perindopril, is an ACE-inhibitor[5] that was approved by the FDA for the treatment of hypertension (high blood pressure) in 1993. Dkt. 114 at 51. In 2005, the FDA approved the drug for use in treating stable coronary artery disease to reduce the risk of

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[3] Relators contend that Solvay chose to market Luvox for the "OC Spectrum" rather than OCD because primary care physicians are less likely to treat "classic" OCD patients, but these physicians often treat patients with milder obsessive and compulsive symptoms, such as hypochondriacs. Dkt. 114 at 42.

[4] On April 20, 1999, seventeen-year-old Eric Harris, who allegedly was taking Luvox, accompanied Dylan Klebold on a killing spree at Columbine High School. Dkt. 114 at 45. According to Relators, defendants advised their sales representatives to tell physicians that Harris had not been using Luvox appropriately. *Id.* The press release issued by SPI stated, "We are aware of the news reports surrounding Eric Harris and the tragedy in Colorado, but have no specific information about his medical history, his doctor's prescription or whether he was taking the medication and, if so, whether he was taking his medication properly." Dkt. 114, Exh. 2.

[5] Aceon was the eleventh ACE inhibitor approved by the FDA. Dkt. 114 at 51. "ACE inhibitors lower blood pressure by inhibiting the activity of angiotensin converting enzyme ("ACE"), which converts angiotensin I to angiotensin II. Angiotensin II causes the muscles surrounding blood to contract, narrowing the blood vessels and increasing the pressure within the vessels. By inhibiting ACE and thereby decreasing the production of angiotensin, the blood vessels dilate and blood pressure is lowered." Dkt. 114 at 51 n.16.

cardiovascular death or myocardial infarction. *Id.* According to Relators, Solvay promoted Aceon and attempted to distinguish it from numerous ACE inhibitor competitors by claiming, with little or no scientific support, that (1) Aceon delivers a structural change in arteries; (2) Aceon provides 24-hour control with no spikes in blood pressure at the end of the dosing cycle; and (3) Aceon lowers the incidence of secondary strokes. *Id.* Solvay allegedly advised doctors that Aceon delivered a structural change in arteries, remodeling them, as opposed to merely lowering blood pressure like other ACE inhibitors.[6] *Id.* at 52. Solvay called this restructuring "arterial wall compliance." *Id.* Relators claim that there was no scientific justification for these claims and that nothing in Aceon's FDA-approved label supports the claims. *Id.* Solvay also allegedly promoted Aceon by claiming that it provided better blood pressure control than competitors because it did not allow a spike in blood pressure during the latter part of the dosing interval.[7] *Id.* at 54. Relators claim that no scientific studies support this claim. *Id.* at 55. Additionally, Solvay allegedly claimed after the completion of the PROGRESS trial that Aceon lowered the incidence of secondary stroke. *Id.* at 59-60. However, according to Relators, the actual results of the PROGRESS trial indicated that the incidence of secondary strokes was only lowered when a rarely used diuretic, indapamide, was added to Aceon, and that, in fact, there was no indication that Aceon added any synergistic effect to the diuretic. *Id.* at 59 (citing Exh. 32).

Relators contend that these tactics induced "[u]nsuspecting doctors" to prescribe Aceon instead of other, less expensive drugs. *Id.* at 61. Relators provide specific examples of doctors who

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[6] Solvay allegedly used the terms "the arterial Ace" and a "tissue Ace" for Aceon to promote its claim that it structurally changed arteries. Dkt. 114 at 53.

[7] According to Relators, this claim was targeted at diabetic patients with hypertension. Dkt. 114 at 54-55.

(1) wrote prescriptions for Aceon after attending talks about arterial wall compliance; (2) wrote prescriptions for Aceon to patients with diabetes, allegedly due to the campaign indicating that Aceon provides better blood pressure control at the end of the dosing cycle—which would be especially significant for patients with renal dysfunction related to diabetes; and (3) wrote prescriptions for Aceon for patients with cerebrovascular disease after attending a program on the PROGRESS study that discussed the off-label use of Aceon as a stroke preventative. *Id.* at 63-65.

3. AndroGel

AndroGel, which is a synthetic testosterone gel, was approved by the FDA in 2000 as being "'indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone'"—specifically, primary hypogonadism and hypogonadotropic hypogonadism.[8] *Id.* at 66 (quoting Exh. 39 (original AndroGel label)). According to Relators, Solvay desired a larger audience for the product, so it formed a strategy to mass market the product for "andropause," which is "a supposed condition of male aging," and for "related ailments such as osteoporosis, sexual dysfunction (as a Viagra substitute), and depression, in male patients with both normal *and* abnormal testosterone levels, with *and* without clinical symptoms." *Id.* at 69. Solvay also allegedly marketed the product for the following off-label uses: "'wasting' in HIV and AIDS patients, women, methadone and other opioid users, diabetics, and those with 'metabolic syndrome'

[8] According to the AndroGel label, primary hypogonadism is "testicular failure due to cryptorchism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals." Dkt. 114, Exh. 39. Men with primary hypogonadism "usually have low serum testosterone levels and gonadotropins . . . above the normal range." *Id.* Hypogonadotropic hypogonadism is an "idiopathic gonadotropin or luteinizing hormone-releasing hormone . . . deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation." *Id.* Men with hypogonadotropic hypogonadism "have low testosterone serum levels but have gonadotropins in the normal to low range." *Id.*

(i.e. obese)." *Id.* Relators present data indicating that specific Texas physicians have prescribed AndroGel for off-label uses, including pediatric use, use in women and HIV/AIDS patients, and andropause and andropause symptoms (including senile depressive disorder, osteoporosis, and sexual dysfunction), after receiving "detailing" from sales representatives.[9] *Id.* at 90-94.

Relators contend that the off-label promotion of Luvox, Aceon, and AndroGel resulted in prescriptions that were filled by pharmacies and that the pharmacies then submitted false claims to government health care plans, including Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, and ADAPs. *Id.* at 107. Relators assert that Solvay's drugs were added to state Medicare and Medicaid formularies after listings in DRUGDEX Information System supported the off-label uses,[10] even though (1) the FDA specifically denied approval for some of the off-label uses listed; and (2) many of the sources cited in DRUGDEX in support of the off-label uses (a) failed to support the efficacy of the drugs for the specific uses, (b) were sponsored

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[9] "Pharmaceutical manufacturers promote their drugs to doctors through a process called 'detailing.'" *Sorrell v. IMS Health Inc.*, __ U.S. __, 131 S. Ct. 2653, 2656 (2011).

[10] Generally, state Medicaid programs only reimburse for drugs that are included on their formularies. *See, e.g., Pharm. Researchers of Am. v. Walsh*, 538 U.S. 644, 651, 123 S. Ct. 1855 (2003); *Dodson v. Parham*, 427 F. Supp. 97, 100 (D.C. Ga. 1977) (defining "formulary" as "a restricted list of drugs for which Medicaid will reimburse provider pharmacists"); Dkt. 114 at 16. States may restrict coverage for drugs when a prescription is not for a "medically accepted indication" or if it is in a category specifically listed in the Medicaid statute—like, for instance, fertility drugs and prescription vitamins. 42 U.S.C. § 1396r-8(d)(1)(B), 1396r-8(d)(2). A "medically accepted indication" is "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act . . . or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in" the Medicaid statute, including the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, the DRUGDEX Information System, and the American Medical Association Drug Evaluations. 42 U.S.C. § 1396r-8(g)(1)(B)(I); 42 U.S.C. § 1396r-8(k)(6). States may also require prior authorization or have preferred drug lists to control against prescriptions for uses that are not medically indicated. *Id.* § 1396r-8(d)(1)(A).

or authored by defendants or raised another conflict of interest, (c) were from studies that were not subject to peer review, (d) involved too few subjects, (e) lacked controls or had some other research flaw, or (f) were authored by a ghostwriter rather than the listed author. *Id.* at 108-09. Relators claim that DRUGDEX listed the uses either because it was deliberately mislead by Solvay or colluded with Solvay. *Id.* at 109.

C. Kickbacks

In addition to the alleged off-label marketing campaign, Relators claim that Solvay "bribed doctors to use its drugs," for on- and off-label uses, with unlawful kickbacks such as "bogus speaker and research fees, resort weekends, cash payments, or Harley Davidson goods," in violation of the AKS. *Id.* at 122. These violations, in turn, allegedly led to the submission by pharmacies and others of false claims to the government for reimbursement for prescriptions. First, Solvay allegedly had several cash schemes whereby it would offer "incentives" to induce physicians to prescribe high volumes of their drugs. *Id.* at 123. For example, Solvay allegedly would (1) pay doctors to complete paperwork on patients taking Solvay drugs, claiming it was in the interest of furthering medical knowledge; (2) provide honoraria to speakers, including one instance in which Solvay paid one doctor $10,500 in one month to speak to fewer than 50 people about Aceon and a total of more than $100,000 in 2000 for speaking engagements; (3) hold these speaker engagements at upscale venues or luxury resorts; (4) pay for the speakers' families to attend these lush events; (5) invite doctors from across the country to fly to a luxury hotel or resort to listen to speakers promote defendants' drugs, paying for airfare, lodging, and an attendance fee, while claiming the physicians were consultants because they were asked to comment on the effectiveness of sales pitches; (6) provide honoraria to physicians who participated in district and regional advisory boards, which

were open venues where off-label indications of defendants' drugs would be discussed; (7) host dinner meetings that ran afoul of the AKS; (8) host Continuing Medical Education ("CME") dinners of off-label topics and, in the early years, provide physicians with a $100 gift certificate for attending the events; (9) arrange for roundtable dinner meetings (or golf outings) hosted by a regional physician; (10) engage in preceptorships during which a physician allows a sales representative to shadow him or her for part of a day for fees ranging from $150 to $1,000; and (11) provide honoraria or grants for bogus clinical trials, studies, or focus panels. *Id.* at 123-37.

Solvay also allegedly offered non-cash kickbacks to induce physicians to prescribe its drugs. Examples include the following perks, which allegedly were received by physicians who were willing to listen to a sales pitch or presentation about Solvay's drugs: Lunch-N-Learn (food from a popular restaurant for the doctor and his or her staff); Dine N' Dash (free meals for physicians to take home to their families from a popular restaurant); Book-N-Dash (gift certificate to a book store); and Flowers-in-a-Flash (free flowers at a local flower shop). *Id.* 137-43.

Relators claim that Solvay provided these kickbacks so that physicians would prescribe the Drugs at Issue to individuals on government health plans. Relators assert that Solvay specifically targeted its marketing schemes to physicians who had a high percentage of patients on government health plans and that it targeted physicians who were on the Medicaid Pharmaceutical and Therapeutic ("P&T") committees of various states by "shower[ing] the member with offers of gifts, dinners, and every kind of bribe in exchange for hearing Solvay's off-label details," in an effort to ensure that the Drugs at Issue were listed on the states' formularies. *Id.* at 116.

Relators provide several examples of prescriptions for Solvay drugs written by physicians after receiving an alleged kickback. *Id.* at 144-46 & Exhs. 131-33.

D. ICD-9 Code Manipulation

Under the Medicaid program, states may only restrict coverage of drugs if (1) "the prescribed use is not for a medically accepted indication"; (2) the drug is in the list contained in subsection 1396r-8(d)(2), which includes, for example, fertility drugs, prescription vitamins, and nonprescription drugs; (3) the drug manufacturer agreed to restrictions in an agreement with Medicaid; or (4) the State excluded the drug from its formulary. 42 U.S.C. § 1396r-8(d)(1)(B). A State can exclude a covered outpatient drug from its formulary "only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation . . . of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(C). However, if a State excludes a drug from its formulary, it must permit coverage of the drug pursuant to a prior authorization program that complies with the Medicaid statute. *See id.* § 1396r-8(d)(4)(D).

Relators claim that Luvox, Aceon, and AndroGel each require prior authorization in some states. Dkt. 114 at 18. In order to obtain prior authorization for drugs that are excluded from state formularies, physicians generally must state why the drug is necessary and provide a written diagnosis. Dkt. 114 at 17. This diagnosis may be written using an ICD-9 code, which is a coding system used by Medicaid to designate diagnoses. Dkt. 114 at 17. Relators allege, upon information and belief, that "certain state Medicaid programs will reimburse for pharmaceutical drugs only if the drug corresponds with a specific diagnosis of the patient, designated by an ICD-9 code recorded by the patient's physician." Dkt. 114 at 18.

Relators assert that Solvay provided ICD-9 codes to physicians in states that required prior authorization before the Drugs at Issue could be prescribed. Relators claim that the provided ICD-9 codes, which were allegedly codes for conditions for which physicians could obtain prior authorization for the drugs, were part of an effort to conceal the real reasons the drugs were prescribed in order to obtain reimbursement for the drugs from Medicare, Medicaid, and other federal healthcare programs. *Id.* at 115, 146. Relators provide examples of physicians that used ICD-9 codes that Solvay allegedly provided when submitting prior authorization forms for state Medicaid programs. *Id.*

II. ANALYSIS: SPI'S MOTION TO DISMISS

SPI moves for dismissal of Relators' claims for violations of the FCA contained in the 4AC, asserting that the claims are insufficiently pled under Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6), that the retaliation claim should be dismissed as time-barred, that the state *qui tam* claims should be dismissed for state-specific pleading deficiencies, and that count 34 should be dismissed because there is no cause of action for a "common fund relief." Dkt. 122.

A. Legal Standards

1. Rule 12(b)(6) Standard

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1964–65 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47, 78 S. Ct. 99 (1957)). In considering a 12(b)(6) motion to dismiss a complaint, courts generally must accept the factual allegations contained in the complaint as true. *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale*

Shipyards, Inc., 677 F.2d 1045, 1050 (5th Cir. 1982). The court does not look beyond the face of the pleadings in determining whether the plaintiff has stated a claim under Rule 12(b)(6). *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, [but] a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 127 S. Ct. at 1964–65 (citing *Sanjuan v. Am. Bd. of Psychiatry and Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994)) (internal citations omitted). And, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 127 S. Ct. at 1965. The supporting facts must be plausible—enough to raise a reasonable expectation that discovery will reveal further supporting evidence. *Id.* at 1959.

2. Rule 9(b) Standard

In addition to meeting the plausibility standard, under Federal Rule of Civil Procedure 9(b), if a party is alleging fraud or mistake, the pleading must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009) (noting that Rule 9(b) does not "supplant" Rule 8(a)). However, this particularity requirement "does not 'reflect a subscription to fact pleading.'" *Id.* (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 178 (5th Cir. 1997)). Instead, pleadings alleging fraud must contain "simple, concise, and direct allegations of the circumstances constituting the fraud, which . . . must make relief plausible, not merely conceivable, when taken as true." *Id.* (internal quotations omitted) (referring to the standard enunciated in *Twombly*).

The Fifth Circuit interprets Rule 9(b) strictly, "requiring a plaintiff pleading fraud to specify the statements contended to be fraudulent, identify the speaker, state when and where the statements

were made, and explain why the statements were fraudulent." *Id.* (quoting *Herrmann Holdings Ltd. v. Lucent Techs. Inc.*, 302 F.3d 552, 564–65 (5th Cir. 2002)). Thus, Rule 9(b) generally requires the complaint to "set forth 'the who, what, when, where, and how' of the events at issue." *Id.* (quoting *ABC Arbitrage Plaintiffs Grp. v. Tchuruk*, 291 F.3d 336, 350 (5th Cir. 2002)). However, "Rule 9(b)'s ultimate meaning is context-specific." *Grubbs*, 565 F.3d at 185. Thus, "[d]epending on the claim, a plaintiff may sufficiently 'state with particularity the circumstances constituting fraud or mistake' without including all the details of any single court-articulated standard—it depends on the elements of the claim at hand." *Id.*

B. Counts I and II: Federal FCA Presentment and False Record Claims

SPI claims that Relators failed to plead their claims of violations of the FCA with the specificity required under Federal Rule of Civil Procedure 9(b), as the off-label promotion claims provide no basis for finding a nationwide epidemic of claims for prescriptions for off-label use written in response to off-label promotion, the unlawful kickback claims do not allege who was paid a kickback or how that kickback led to the submission of a false claim, and the ICD-9 Code manipulation claims do not connect any false claims to the alleged manipulated codes. Dkt. 122 at 11. SPI additionally claims that, under Federal Rule of Civil Procedure 12(b)(6), Relators' allegations of FCA violations relating to unlawful kickbacks fail because Relators do not plead a viable false certification theory, and the violations with regard to off-label promotion and ICD-9 manipulation fail because Relators do not allege facts showing a material falsity that rendered pharmacy prescription claims nonreimbursable. *Id.* at 12.

Relators argue that the allegations in the 4AC lead to a strong inference that at least one false claim was submitted to the Government, and that Rule 9(b) does not require that the complaint

allege the time, place, and contents of the actual claim submissions. Dkt. 131. As for SPI's 12(b)(6) arguments, Relators contend that kickback-tainted claims are inherently false, so pleading false certification in not necessary. *Id.* They claim, however, that, regardless, they have plausibly pled that physicians, pharmacists, and third-party payers made false certifications representing to the Government that they had complied with all federal and state laws and regulations relating to fraud, including the AKS. Dkt. 131 at 26. Relators additionally argue that they have plausibly alleged that off-label and ICD-9 code claims were not reimbursable.

1. The FCA

The FCA provides for civil suits brought by either the Attorney General or private persons, known as "relators," "who serve as a 'posse of *ad hoc* deputies to uncover and prosecute frauds against the government.'" *Grubbs*, 565 F.3d at 184 (quoting *United States ex rel. Milam v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir. 1992)). If a private person desires to bring a suit under the FCA as a relator, the suit is known as a *qui tam* suit. *See id.* The relator must file the *qui tam* action in the name of the Government, under seal, and serve the complaint and the material evidence on the Government. 31 U.S.C. § 3730(b) (2006). The complaint must remain under seal for 60 days, during which the Government may either elect to intervene and proceed with the action or notify the court that it declines to intervene. *Id.* If the Government elects not to intervene, the relator has the right to proceed with the action.[11] *Id.* § 3730(c)(3).

[11] If the Government proceeds with the action, the relator is entitled to receive between 15 and 25 percent of the proceeds of the action or settlement. *Id.* § 3730(d)(1). If the Government does not proceed with the action, the relator, generally, is entitled to receive between 25 and 30 percent of the proceeds of the action or settlement. *Id.* § 3730(d)(2). The percentage is reduced to ten percent or less if the action is based primarily on information provided by sources other than the relator. *See* 31 U.S.C. § 3730(d)(1). Under either scenario, the relator is also entitled to reasonable expenses and attorneys' fees. *Id.* § 3730(d)(1)-(2). If the Government does not proceed with the

> Under the current version of section 3729(a)(1) of the FCA,
>
> [A]ny person who—
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> . . .
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C.A. § 3729(a) (Supp. 2011). Under the previous version of the relevant subsections of section 3729(a),

> [A]ny person who--
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; [or]
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> . . .
> is liable to the United States Government . . . .

31 U.S.C. § 3729(a) (2006). The amendments, which were enacted in 2009, generally apply to conduct on or after May 20, 2009. However, the amendment to the previous subsection 3729(a)(2), which renumbered the subsection as 3729(a)(1)(B) and changed the text, "applies retroactively to all claims pending on or after June 7, 2008." *United States ex. rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 & n.1 (5th Cir. 2010). The Fifth Circuit interprets "claims" to mean cases or causes of action rather than claims for reimbursement. *See id.* Since this case was pending on June 7, 2008, the new subsection 3729(a)(1)(B) applies. *See id.* (applying the new subsection because the case was pending on June 7, 2008); *see also United States ex rel. Patton v. Shaw Servs., L.L.C.*,

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action and the defendant prevails, the court may award the defendant reasonable attorneys' fees and expenses if it finds "the action was clearly frivolous, clearly vexatious, or brought primarily for the purposes of harassment." *Id.* § 3730(d)(4).

418 Fed. App'x 366 (5th Cir. Mar. 17, 2011) (noting that the relator's complaint was "pending" after the effective date of the new subsection, indicating that the new subsection should apply, but determining that the difference between the old and new subsections was irrelevant under the facts of that case). *But see United States ex rel. Bennett v. Boston Scientific Corp.*, 747 F. Supp. 2d 745, 763 (S.D. Tex. 2010) (collecting district court cases) (finding that the revised version of the subsection did not apply to a case that was pending on June 7, 2008, because Congress made the revision retroactive to *claims* pending on June 7, 2008, and "claims" under the FCA means claims for reimbursement, not cases or causes of action). However, the older version of 3729(a)(1) (now 3729(a)(1)(A)) applies.[12]

The Fifth Circuit has summarized the requirements of a claim under the FCA: "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the Government." *Steury*, 625 F.3d at 267. As for scienter, the relevant provisions require "knowing" conduct, and the FCA defines "knowing" and "knowingly" as having "actual knowledge of the information," acting "in deliberate ignorance of the truth or falsity of the information," or acting "in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A); *see also Steury*, 625 F.3d at 267 (applying this definition). "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4) (2009) (defining "material" for conduct after May 20, 2009); *United States ex rel. Longhi v. United States*, 575 F.3d 458, 470 (5th Cir. 2009)

[12] In order to be clear, the court will refer to the amended subsection 3729(a)(2), which is now 3729(a)(1)(B) and applies to this case, as subsection 3729(a)(1)(B) (2009). And the court will refer to the previous version of subsection 3729(a)(1), which is the subsection that applies to this case, as 3729(a)(1) (2006). The court will refer to the previous version of subsection 3729(a)(2) as 3729(a)(2) (2006).

(requiring materiality under both subsection 3729(a)(2) (2006) and 3729(a)(1)(B) (2009) and defining "materiality" as having a "natural tendency to influence, or . . .capable of influencing, the decision of the decisionmaking body to which it was addressed" (citations and quotations omitted)). The "natural tendency" test requires "that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is the result of indirect or intangible actions on the part of the Defendants." *Longhi*, 575 F.3d at 470. Thus, the statements must "have the potential to influence the government's decisions." *Id.*

2. Rule 9(b)

SPI argues that Relators' FCA claims stemming from alleged off-label promotion, kickbacks, and ICD-9 code manipulation should be dismissed under Rule 9(b) because Relators fail to set forth the "'who, what, when, where, and how of the alleged fraud.'" Dkt. 122 at 12 (quoting *Steury*, 625 F.3d at 266). SPI contends that Relators must plead the specifics of a scheme to cause claims to be submitted for nonreimbursable uses *and* details of the claims. *Id.* at 15. Relators argue that, under Rule 9(b), the complaint must set forth the time, place, contents, and identity surrounding the *fraud*, but they contend that there is no requirement to plead the time, place, contents, and identity of the *actual submissions* to the Government. Dkt. 131 at 6.

The Fifth Circuit squarely addressed how much specificity is required under subsections 3729(a)(1) and (2) (2006) of the FCA in *Grubbs*. In *Grubbs*, James Grubbs, a psychiatrist who had worked for Memorial Hermann Baptist Beaumont Hospital (the "Hospital"), brought a *qui tam* complaint against the Hospital and seven physicians who worked at the hospital. *Grubbs*, 565 F.3d at 183. Grubbs alleged that the physicians at the Hospital saw patients only on an "as needed" basis,

when the nursing staff felt it was appropriate, but the bill reflected a regular "face-to-face" hospital visit. *Id.* at 184. The *Grubbs* defendants filed a motion to dismiss for failure to comply with the pleading requirements of Federal Rule of Civil Procedure 9(b), and the magistrate judge recommended dismissal. *Id.* at 185. The district court adopted the magistrate judge's recommendation, and Grubbs appealed. *Id.*

The Fifth Circuit first noted that a complaint filed under the FCA must meet the heightened pleading requirement of Rule 9(b). *Id.* Under Rule 9(b), a party alleging fraud or mistake "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) "has long played [a] screening function, standing as a gate-keeper to discovery, a tool to weed out meritless fraud claims sooner than later." *Grubbs*, 565 F.3d at 185. "Rule 9(b) does not 'reflect a subscription of fact pleading' and requires only 'simple, concise, and direct' allegations of the 'circumstances constituting fraud,' which after *Twombly* must make relief plausible, not merely conceivable, when taken as true." *Id.* at 186 (quoting *Williams*,112 F.3d at 178). The Fifth Circuit, which "traditionally required that a fraud complaint include 'the time, place and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby,'" instructed that the Rule's requirements are context-specific and "thus there is no single construction of Rule 9(b) that applies in all contexts." *Id.* at 188 (quoting *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308 (5th Cir. 1999)).

The *Grubbs* court determined that, in the context of a claim under subsection 3729(a)(1) (2006) of the FCA, the Act does not require the litigant to prove reliance or damages, it "is adequate to allege that a false claim was knowingly presented regardless of its exact amount; the contents of the bill are less significant because a complaint need not allege that the Government relied on or was

damaged by the false claim." *Id.* at 189. A "plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted." *Id.* at 190. The Fifth Circuit held that "to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.*

The Fifth Circuit determined that the *Grubbs* complaint against the individual doctors pursuant to section 3729(a)(1) (2006) was sufficient to satisfy the requirements of Rule 9(b) because Grubbs set forth the details of the scheme as well as the specific dates that each doctor falsely claimed to have provided services to patients as well as, in some instances, the type of medical services or the procedural terminology code that would have been used to bill. *Grubbs*, 565 F.3d at 191-92. The Fifth Circuit noted that the list of dates that specified, unprovided services were recorded "amounts to more than probable, nigh likely, circumstantial evidence that the doctors' fraudulent records caused the hospital's billing system in due course to present fraudulent claims to the Government." *Id.* at 192. "That the fraudulent bills were presented to the Government is the logical conclusion of the particular allegations in Grubbs' complaint even though it does not include exact billing numbers or amounts." *Id.*

With regard to the claims under subsection 3729(a)(2) (2006), the Fifth Circuit noted that, to satisfy subsection 3729(a)(2) (2006), the defendant must make "a false record or statement for the purpose of getting a false or fraudulent claim paid by the Government." *Grubbs*, 565 F.3d at 193. Thus, "the recording of a false record, when it is made with the requisite intent, is enough to satisfy

the statute." *Id.* There is no need to infer that the record caused a claim to be presented. *Id.* Therefore, Grubbs' allegations that two of the physicians explained how the nursing staff wrote notes relating to face-to-face visits with patients that were actually only seen on an as-needed basis, that the nursing staff attempted to assist him in recording such notes, and that certain doctors recorded false notes on specific dates, were sufficient to state a claim for fraud under subsection 3729(a)(2) (2006) and should not have been dismissed at the pleading stage. *Id.*

Under the subsection 3729(a)(1)(B) (2009), the phrase "to get a false or fraudulent claim paid or approved by the Government," which was used in the previous version, has been replaced with "material to a false or fraudulent claim." *Compare* 31 U.S.C. § 3729(a)(1)(B) (2009), *with* 31 U.S.C. § 3729(a)(2) (2006). The first part of the subsection, "knowingly makes, uses, or causes to be made or used, a false record or statement," remains unchanged. While the *Grubbs* court did not require presentment of the claim or subsection 3729(a)(1) (2006) claims, it is unclear whether the new version requires presentment.

Thus, in this case, in order for the subsection 3729(a)(1) (2006) claims to survive Solvay's Rule 9(b) challenge, the 4AC must allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." The "logical conclusion" of the allegations must be that fraudulent claims were submitted to the government. And, the subsection 3729(a)(1)(B) (2009) claims can survive only if the 4AC alleges that Solvay made a false record or statement that was material to a false or fraudulent claim, i.e. that had the potential to influence the government's decision. The court turns first to the subsection 3729(a)(1) (2006) claims.

a. Subsection 3729(a)(1) (2006) Off-Label Promotion Claim

SPI argues that, under *Grubbs*, Relators must pair their allegations of a scheme with "details 'such as dates and descriptions of recorded, but unprovided, services and a description of the billing system that the records were likely entered into.'" Dkt. 122 at 15 (quoting *Grubbs*, 565 F.3d at 190-91). SPI states that Relators have not identified any instance in which a physician actually wrote a prescription for a federal program patient because of an alleged off-label promotion scheme *and* a pharmacy submitted a claim for that off-label prescription. *Id.* Relators, on the other hand, claim that the 4AC provides reliable indicia that claims were actually submitted and that they are not required to "plead the who, what, when, where, and how *of a claim*." Dkt. 131 at 7. Relators claim that they have pled the who, what, when, where, and how of the alleged *fraudulent scheme* in detail, including alleging the identities of brand managers and other executives involved in the alleged scheme, discussion of the official brand strategy, alleged illegal tactics endorsed for achieving off-label sales, and informal and formal selling practices. Dkt. 131 at 8. Relators contend that this information is sufficient, alone, to state a claim under *Grubbs*; however, they claim they have pled "more than was required," as they have pled "ample 'representative samples' of off-label claims submitted to Medicaid for each of the three drugs" at issue. *Id.* at 12 (citations omitted).

1. Reliable indicia of that the off-label marketing scheme caused physicians to write off-label prescriptions

The 4AC includes substantial allegations that Texas physicians wrote off-label prescriptions for Luvox, AndroGel, and Aceon for federal program patients. *E.g.*, Dkt 114 at 50, 63, 90. SPI claims, however, that the 4AC fails to assert that the alleged off-label promotion caused a specific physician or physicians to write these prescriptions. Dkt. 122 at 17-18. SPI contends that this court,

in *Bennett v. Medtronic*, "rejected similarly lacking allegations just months ago." Dkt. 122 at 18 (citing *Bennett*, 747 F Supp. 2d 745).

In *Bennett*, the court considered whether to dismiss a *qui tam* FCA claim alleging that off-label promotion of a medical device caused physicians and hospitals to submit false Medicare and Medicaid claims. 747 F. Supp. 2d at 748. The court determined that the relators "failed to plead with sufficient particularlity the alleged false claims, [as the] relators [did] not identif[y] any [of the defendant's] employees who engaged in off-label promotion nor specific physicians or hospitals who received the promotions." *Bennett*, 747 F.2d at 779. Additionally, the *Bennett* relators did not identify any physicians to whom the defendant promoted its medical device for off-label use who actually submitted false claims to the Government for off-label use. *Id.* The *Bennett* court distinguished *Grubbs*, finding that, unlike the plaintiffs in *Grubbs*, the *Bennett* relators' complaint did "not sufficiently allege[] that by promoting off-label use, [the defendant] *caused* the submission of false claims and is liable under the FCA." *Id.* at 780-81 (emphasis added).

Here, Relators' contentions relating to the off-label promotion scheme paired with the promotion and prescription details outlined relating to individual Texas physicians in the 4AC are reliable indicia that permit a strong inference that the off-label promotion scheme caused at least some physicians to write off-label prescriptions for Luvox, Aceon, and AndroGel. Unlike the complaint in *Bennett*, which did not identify any physicians who received the alleged off-label promotions (*see* 747 F. Supp. 2d at 779), the instant complaint identifies specific physicians in Texas who prescribed Luvox, Aceon, and AndroGel to Medicaid patients for off-label use after sales representatives "pitched" these uses during sales calls or who attended presentations that specifically discussed the off-label uses. Dkt. 114 at 50.

For example, on December 31, 1999, a sales representative documented a "pitch" to a doctor in which the representative discussed geriatric safety of Luvox based on pediatric safety. This physician prescribed Luvox to a 74-year-old patient for anxiety on March 11, 2000, and to a 78-year-old patient for paranoia on September 7, 2000; these are both uses that are not indicated on Luvox's label.[13] Dkt. 114 & Exh. 18.

With regard to AndroGel, the 4AC identifies, for example, two physicians who wrote Medicaid prescriptions for AndroGel for off-label conditions associated with "andropause" after receiving and being encouraged to use the ADAM questionnaire from Solvay, which is aimed at detecting "andropause." Dkt. 114 at 92-93 & Exhs. 72, 74. The 4AC additionally provides examples of physicians who received extensive detailing from Solvay about AndroGel and subsequently prescribed AndroGel for off-label uses. Dkt. 114 at 90-94. Relators do not provide any details about what the sales representatives said during the sales calls, so the court does not rely on these examples alone to determinate that Relators have provided reliable indicia that off-label promotion led to off-label claims, but these examples buttress the examples provided that are linked to specific promotional messages, and, when paired with these specific examples and all of the details provided about the off-label campaigns, constitute reliable indicia permitting the necessary inference. Thus, there is specific support for Relators' contention that physicians indeed wrote prescriptions for off-label uses of AndroGel after receiving off-label promotion.

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[13] SPI claims that the only allegations in the 4AC of specific physicians prescribing Luvox after receiving off-label pitches are (1) a physician who received an off-label message about Luvox in December 1999 and prescribed it between 7 and 20 months later; and (2) a physician who received an off-label message about Luvox and prescribed it to two patients over the next three years. Dkt. 122 at 17. These are, indeed, the only examples contained in the excerpt of the chart that is contained within the actual complaint itself. However, the 4AC clearly points to an attached summary chart that contains several more examples. *See* Dkt. 114 at 50-51.

There is less evidence of causation in the 4AC with regard to Aceon, but the court finds that the examples provided reliably indicate that Solvay's off-label marketing of Aceon led to off-label prescriptions. For instance, the 4AC identifies several physicians who began prescribing Aceon extensively to Texas Medicaid patients after attending talks in which arterial wall compliance and the diabetic kidney were discussed, yet had never prescribed Aceon before attending the talks.[14] Dkt. 114 at 63 & Exh. 35, 36. SPI argues that this example is not reliable because the prescriptions were "for an unidentified indication." Dkt. 122 at 16. Relators' attached charts, however, provide diagnosis information. *See* Dkt. 114, Exh. 36. Moreover, the chart at Exhibit 36a provides a list of prescriptions of Aceon written for diabetic patients by these doctors, and the chart at Exhibit 36b provides a list of prescriptions for Aceon written for stroke patients by these doctors. Dkt. 114 at 63 & Exh. 36a-b & Exh. Index. Relators' two most extensively alleged off-label promotion claims for Aceon (24-hour control/diabetic kidney and PROGRESS/stroke prevention) were allegedly

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[14] Relators provide examples of physicians who prescribed Aceon after Solvay "rolled out" the PROGRESS campaign, but the court does not find these examples to be reliable indicia that false claims were actually submitted. There is no indication that these physicians were recipients of any of Solvay's alleged off-label marketing of Aceon for stroke-related diagnoses, and the physicians could have decided to prescribe the drug for other reasons, including, for example, learning about the PROGRESS trial from other sources, such as the publication of the study in *The Lancet*.

The study was published in *The Lancet* in 2001, and the "interpretation" section of the study states: "Combination therapy with peridopril and indapamide produced larger blood reductions and larger risk reductions than did single drug therapy with perindopril alone. Treatment with these two agents should now be considered routinely for patients with a history of stroke or transient ischaemic attack, irrespective of their blood pressure." Dkt. 114, Exh. 32 (PROGRESS Collaborative Group, *Randomised Trial of a Perindopril-Based Blood-Pressure Lowering Regimen Among 6105 Individuals with Previous Stroke or Transient Ischaemic Attack*, 358 Lancet 1033 (2001)).

According to Relators, the DRUGDEX entry for Aceon cites the PROGRESS study, noting that Aceon may be used for patients with strokes. Dkt. 114 at 62. Relators claim that DRUGDEX originally listed Aceon as a treatment for the prevention of secondary stroke in the "most supportive category." It was later "downgraded . . . into a middle range" category, which recommended its use for prevention of secondary stroke only "in some cases." *Id.*

specifically targeted at physicians with diabetic and stroke patients. Dkt. 114 at 53-60. The court finds that the examples when considered in light of the other information in the 4AC provide reliable indicia that Solvay's off-label promotion of Aceon caused physicians to prescribe Aeon for off-label uses.

SPI also argues that Relators must provide details of instances in which SPI allegedly promoted each Drug at Issue to a physician for *each alleged off-label use* and caused a physician to write a prescription for that off-label use that was ultimately filled. Dkt. 122 at 15-17. Relators have provided representative examples for multiple alleged off-label uses for these drugs, but they have not provided examples of every alleged off-label use. Relators have alleged a nationwide off-label promotion scheme involving multiple drugs with multiple off-label uses, and with such an extensive scheme, it is not practical to provide specific details about prescriptions for every alleged off-label use at the pleading stage. *Grubbs* simply requires reliable indicia that lead to a strong inference that claims were actually submitted. Here, the court finds that the allegations relating to the off-label promotion scheme for each off-label use paired with the examples that show that some of the off-label promotion led to prescriptions for some of the off-label uses meets that standard. Moreover, the heightened 9(b) pleading standard "stems from the obvious concerns that general, unsubstantiated charges of fraud can do damage to a defendant's reputation." *Guidry v. Bank of LaPlace*, 954 F.2d 278, 288 (5th Cir. 1992). In the court's view, the lack of examples for some of the off-label promotion claims does not threaten SPI's reputation with unsubstantiated charges given the number of examples of promotion for off-label uses that are substantiated.

2. Reliable Indicia Off-Label Claims Submitted to Government

SPI claims that "[g]eneral off-label promotion allegations that are not linked to particularized details reliably demonstrating that false claims resulted do not state a FCA claim." Dkt. 122 at 17. SPI contends that Relators must allege the submission of a claim for payment to the government for a non-reimbursable, off-label use as a result of improper off-label promotion. *Id.* SPI argues that Relators' failure to provide "details like dates and descriptions of pharmacies submitting claims" is fatal to their claim. *Id.* at 16.

Relators claim, on the other hand, that the 4AC contains sufficient reliable indicia to raise a strong inference that claims arising from Solvay's alleged schemes were actually submitted to the government. Dkt. 131 at 8. First, Relators indicate that they have intimate knowledge of Solvay's off-label schemes due to their positions as district managers in the company. *Id.* at 9. Relators claim that their "supervisors trained them in various off-label tactics and directed them to teach them in turn to their representatives." *Id.* at 9. Second, Relators claim that Solvay specifically targeted physicians who prescribed to patients on government health programs as well as physicians who were on state P&T committees, which made decisions about which drugs to include on state formularies, so that physicians would prescribe the Drugs at Issue to patients on government health programs and the government would provide reimbursement for the prescriptions. *Id.*

SPI cites *United States ex rel. Rafizadeh v. Continental Common, Inc.*, 553 F.3d 869 (5th Cir. 2008), in support of its contention that the allegations in the 4AC are insufficient under Rule 9(b) because they are not particularized enough to demonstrate that false claims were actually submitted to the government. In *Rafizadeh*, the Fifth Circuit considered whether a district court erred in dismissing, with prejudice, a *qui tam* suit alleging that landlords overcharged government entities

on lease agreements. 553 F.3d at 872. The pleading in *Rafizadeh* indicated that the defendants knowingly submitted false claims for rental invoices to the state departments in charge of the program, which caused them to submit false claims to the federal government, which was obligated to fund the state departments' budgets. The Fifth Circuit noted that "the linchpin of an FCA claim is a false claim" and determined that the allegation that claims were submitted was insufficient under Rule 9(b) because it did "not describe what statements were contained in the budget, who prepared it, or what role it played in securing funding from the federal government. *Id.* at 873. Thus, the details of the "claims" were not sufficiently particularized. *Id.*

Here, like in *Rafizadeh*, the details provided of the actual claims submitted to government payers are not substantial. However, there are enough other facts alleged that reliably indicate that false claims were submitted to government agencies. The 4AC provides many details that strongly suggest that Solvay's alleged off-label marketing scheme resulted in claims being submitted to the government for payment. First, it is clear that there were claims submitted to government payers for off-label uses of the Drugs at Issue, as Relators provide claims data indicating that Texas physicians wrote prescriptions for off-label uses of the Drugs at Issue to patients on Texas Medicaid and that these prescriptions were filled. *See* Dkt. 114 at 50, 64-65, 93-94. Second, the 4AC indicates that off-label prescriptions were likely submitted to government payers because Solvay allegedly specifically targeted its marketing to physicians that prescribe drugs to patients who are on government health programs. *See id.* at 107, 111-22. For example, Relators allege that Solvay put stickers on samples reminding physicians that the drugs were covered by Medicaid and that Solvay district managers used prescribing information data to shape their marketing pitches to individual physicians who wrote prescriptions to individuals on Medicaid. *Id.* 113-14. Solvay also

allegedly targeted physicians who were members of state P&T committees, in an attempt to obtain favorable treatment on state formularies. *Id.* at 116-19. Taken together, these allegations raise a strong inference that claims were actually submitted to the government for reimbursement.

In sum, the 4AC plausibly alleges a nationwide off-label promotion scheme to submit false claims for each of the Drugs at Issue and reliable indicia leading to a strong inference that claims were actually submitted, and thus survives SPI's Rule 9(b) challenges. SPI's motion to dismiss based on failure to allege the off-label promotion claims with particularity is DENIED. SPI's other requests for dismissal relating to off-label promotion are made pursuant to Rule 12(b)(6) rather than 9(b) and will accordingly be analyzed after the court addresses SPI's Rule 9(b) challenges relating to kickbacks and ICD-9 codes.

b. Alleged Kickbacks

In the 4AC, Relators contend that Solvay's alleged unlawful attempts to induce physicians to prescribe its drugs include a scheme to provide kickbacks to physicians for prescribing the Drugs at Issue. Relators claim that "Solvay's off-label marketing and kickbacks schemes went hand-in-hand to induce high-Medicaid prescribing-physicians to prescribe and continue prescribing Solvay drugs." Dkt. 131 at 19. Relators assert that "Solvay bribed doctors to use its drugs" with "bogus speaker and research fees, resort weekends, cash payments, or Harley Davidson goods." Dkt. 114 at 122. Relators contend that Solvay's provision of these kickbacks was a violation of the Medicare-Medicaid Anti-Fraud and Abuse Amendments ("Anti-Kickback Statute" or "AKS") and that any claims resulting from the unlawful kickbacks were in violation of the FCA.

SPI moves for dismissal of Relators' kickback claims under Rule 9(b), claiming that the 4AC fails to provide "any details about any false claim resulting from the variety of kickback 'schemes'"

that Relators allege and that the 4AC provides no details upon which to base a strong inference that false claims were submitted. Dkt. 122-2 at 19 (citing *Grubbs*, 565 F.3d at 190-91). SPI argues that in order to meet the *Grubbs* reliable indicia standard, Relators must allege "when SPI paid a physician an unlawful kickback with the requisite intent to cause a prescription to be written for one of those drugs for a government program patient, what prescriptions were caused by that kickback, and how the government was billed for those prescriptions." Dkt. 139 at 3-4. SPI claims that no allegations in the 4AC connect the alleged kickbacks to a resulting prescription from a doctor or a pharmacy's claim for payment. Dkt. 122 at 19-20. As for the specific examples that are contained within the 4AC, SPI notes that they only relate to "a handful of physicians" who allegedly prescribed a Solvay drug within four years of receiving a speaker fee for participating in Solvay speaker programs. *Id.* at 20. Solvay asserts that these physicians are all from Texas and therefore offer no support for allegations outside of Texas and that many of the allegations involve prescriptions that were written years after the alleged kickback and therefore provide no reliable link. *Id.* at 20-21. Additionally, SPI asserts that the 4AC makes no mention of any claims allegedly resulting from several of the specific types of kickbacks, so the claims relating to these types of kickbacks are not particularized in accordance with Rule 9(b). Dkt. 122 at 19.

Despite the fact that the claims data that the 4AC uses to link specific physicians who allegedly received kickbacks to Medicaid prescriptions for the Drugs at Issue are all from Texas, Relators have alleged enough details of a geographically diverse kickback scheme to reliably indicate that there was a nationwide kickback scheme.[15] They have alleged their own personal

[15] While there are not allegations relating to every state in the union, the court finds that enough states are linked with kickbacks in the 4AC to reliably indicate that the alleged scheme was nationwide.

knowledge of the kickback scheme as Solvay sales managers, and they have provided details of specific types of kickbacks provided in different parts of the country, including an internal Solvay audit report that indicates various types of gifts were given to physicians in Louisiana and Texas, information about physicians in West Virginia to whom King, in his capacity as a sales representative, provided kickbacks (in the form of speaker's fees), and information about roundtables at upscale resorts in different areas of the country where Solvay allegedly paid for physicians' and their families' rooms, meals and activities, golf, and a show in the evening, as well as specific allegations relating to physicians receiving kickbacks in Virginia, Georgia, North Carolina, and Alabama. Dkt. 114 at 10, 102-03, 124-25, 140-44 & Exh. 1; *See* Dkt. 131 at 17. The 4AC alleges that some events, such as resort weekend in Arizona involving only "six hours of meetings and plenty of time for golf" were organized "out of headquarters." Dkt. 114 at 124-25.

The 4AC reliably indicates that the alleged kickbacks resulted in prescriptions to patients on government health plans and leads to a strong inference that claims were actually submitted. First, the 4AC indicates that the physicians Solvay targeted to receive off-label promotion were also targeted for kickbacks—physicians who prescribed to patients on Medicaid and other government health plans and physicians who were on state P&T committees. Dkt. 114 at 116. For instance, Solvay managers allegedly considered doctors' Medicaid prescription volume when determining which doctors to target for kickbacks. Dkt. 114 at 113-15. Solvay also specifically targeted members of states' Medicaid P&T committees in an effort to obtain placement of their drugs on the state formularies, allegedly showering the committee members with offers of gifts, dinners, and bribes. Dkt. 113 at 116. Relators provide a specific example of a Solvay Regional Business Director who "encouraged his sales team members to 'wine and dine' these doctors, even doctors

who never prescribed Solvay drugs or were retired," in an obvious attempt to influence P&T committees. *Id.* at 117.

Moreover, the specific examples that Relators provide of physicians who prescribed the Drugs at Issue after receiving alleged kickbacks demonstrate that physicians who received alleged kickbacks in fact *did* write prescriptions for patients on Medicaid. Solvay argues that the provided examples are not sufficient because (1) the examples are all from Texas and thus do not support Relators' nationwide contentions; (2) there are not examples for each of the alleged kickback schemes contained within the 4AC; and (3) the prescriptions in the examples are not temporally linked to the alleged kickbacks. Dkt. 122 at 20-21; 139 at 9.

First, the examples of Texas physicians who prescribed Solvay drugs after receiving kickbacks lead to a strong inference that this also happened in other parts of the country. Solvay claims that the district court for the Eastern District of Arkansas, in *United States ex rel. Thomas v. Bailey*, No. 4:06CV00465 JLH, 2008 WL 4853630, at *6 (E.D. Ark. Nov. 6, 2008), held that a relator who identified only a "handful of physicians" who allegedly received kickbacks did not support the allegation of a nationwide policy. Dkt. 122 at 19. However, in *Thomas* the relator specified false claims with respect to only two physicians. 2008 WL 4853630, at *6. The alleged false claims specified in this case are significantly more extensive. *See* Dkt. 114 at 144-46 & Exhs. 131-33. Moreover, the 4AC alleges that some of the kickback schemes were organized by company headquarters and implemented nationwide. *See, e.g.*, Dkt. 114 at 124-25.

Second, while Relators have not provided representative examples of false claims submitted for every alleged type of kickback scheme in the 4AC, the different schemes are alleged in detail, and there are representative examples that some of these alleged schemes resulted in claims to

government health care programs. *See* Dkt. 114 at 122-46. Thus, there are reliable indicia that false claims resulting from kickbacks were submitted to government health care programs. Specific examples linking prescriptions to every type of kickback alleged is unnecessary, as Solvay has sufficient notice of the types of kickbacks alleged and can prepare its case accordingly.

Third, the specific Medicaid prescriptions for Aceon described in the 4AC are sufficiently linked to kickbacks as the physicians who wrote the prescriptions allegedly received kickbacks. The 4AC provides examples of physicians who prescribed Aceon within one to two months of attending programs offering cash kickbacks for prescribing Aceon. *See id.* at 136, 145 & Exh. 132. Solvay claims that the 4AC contains no link between a kickback and prescriptions that the physicians wrote years later, and it cites *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 824 (E.D. Tex. 2008) in support of its position. In *Foster*, the federal district court in the Eastern District of Texas dismissed a kickback claim because it was "without information to suggest that kickbacks induced any recommendation connected to . . . federal healthcare patients." 587 F. Supp. 2d at 824. The *Foster* relator provided information about alleged kickbacks but did not provide one factual detail or example of a claim resulting from the kickbacks. *Id.* Here, Relators provide details and examples. Dr. Fifteen, for example, had never written a prescription for Aceon before February 2000, when he attended his first Solvay City event; Solvay City is a program whereby physicians were allegedly paid cash for providing feedback about Solvay sales pitches. Dkt. 114 at 63-64, 137. After this initial event, Solvay allegedly paid Dr. Fifteen to fly to Milan for the unveiling of the PROGRESS results and, thereafter, Solvay paid Dr. Fifteen to give presentations about PROGRESS. Dkt. 114 at 64 & Exhs. 37, 38. Dr. Fifteen wrote 365 Medicaid prescriptions for Aceon between February 2000 and June 2005. Dkt. 114 at 64 & Exh. 75.

The examples of kickbacks to physicians who prescribed AndroGel to Medicaid patients are not as extensive as the examples for Aceon. The examples are mainly of kickbacks for speaker programs for Aceon. For instance, Dr. Fifteen received kickbacks for speaking about Aceon, but he began prescribing AndroGel shortly after the kickbacks for the Aceon programs began. Dkt. 114, Exh. 75. The 4AC contains several other examples of physicians who received kickbacks for various Aceon events and began prescribing AndroGel as well as Aceon. Dkt. 114, Exh. 133 & Index. These examples, while not specific to AndroGel alone, link kickbacks to AndroGel prescriptions for Medicaid patients and are reliable indicia that claims for reimbursement for AndroGel prescriptions resulted from kickbacks.

With regard to Luvox, the examples of Medicaid prescriptions written for Luvox provided by Relators are, as Solvay suggests, too distant in time from the dates of the alleged kickbacks or otherwise do not reliably indicate that the two are related. The specific examples of Texas physicians who allegedly received kickbacks for prescribing Luvox indicate that the physicians received some type of speaker fees in 1996 or 1997; these physicians did not begin writing prescriptions for Luvox for Medicaid patients until November 1999. *See* Dkt. 114 at 144 & Exh. 131. Another example provided by Relators of physicians receiving kickbacks for prescribing Luvox is Dr. Twenty-Six. Solvay, through Relator King, provided fees ranging from $750 to $1000 per event to Doctor Twenty-Six, who was originally the eighth highest prescriber of Luvox in the country, to give speeches about Luvox. Relators state that a "turning point with Dr. Twenty-Six came with a speaker's event at Princeton Community Hospital in Princeton, WV, in 1995 or 1996 at which [Dr. Twenty-Six] spoke with local psychiatrists and nurses at the hospital. Before the event, 2.5 to three percent of Dr. Twenty-Six's prescriptions were for Luvox, but after that October

1, 2011, Dr. Twenty-Six began prescribing four to 4.5 percent of his patients Luvox." Dkt. 114 at 102. These prescriptions are linked sufficiently in time to the alleged kickbacks, but they are not linked sufficiently to Medicaid. According to King, Dr. Twenty-Six was in an economically depressed area in West Virginia with a high proportion of Medicaid enrollees. However, there is no allegation that Dr. Twenty-Six was even a Medicaid provider. *Cf. United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003) (holding that the *qui tam* relators did not plead their kickback claims with particularity because the allegations were not linked to Medicare patients, in general, and were "too vague to give defendants notice of the relationship between the alleged kickbacks and the submission of claims to Medicare"). The court therefore holds that the kickback claims relating to Luvox do not meet the Rule 9(b) pleading standard.

In sum, the court holds that the 4AC reliably indicates that Solvay's alleged kickback practices were crafted with the intent that physicians would write prescriptions for Solvay drugs and that these prescriptions would be reimbursed by Medicaid or other government payers. The examples of physicians who allegedly received kickbacks from Solvay and later wrote prescriptions for AndroGel and Aceon are reliable indicia that the kickbacks caused the Medicaid claims. However, the examples of Luvox claims are not sufficiently linked to alleged kickbacks to raise a strong inference that claims were actually submitted, and, while there do not necessarily have to be specific examples if the allegations lead to a strong inference that claims resulting from the kickbacks were submitted, there are not enough other details alleged to raise that inference. Accordingly, SPI's motion to dismiss Relators' kickback claims based on kickbacks for Aceon and

AndroGel is DENIED, but its motion to dismiss Relators' kickback claim based on kickbacks for Luvox is GRANTED.

c. Alleged ICD-9 Code Manipulation

SPI contends that Relators' claims relating to ICD-9 code manipulation should be dismissed because there are no reliable indicia that claims were submitted to the Government with ICD-9 codes that were improper for a patient's diagnosis or treatment plan. Dkt. 139 at 9. Relators contend that the 4AC has supplied all of the particulars required by *Grubbs* with regard to the ICD-9 code scheme and have supplied specific examples as well. Dkt. 131 at 20. Relators state that they have alleged specific codes urged on specific physicians and described specific exchanges between sales representatives and physicians. *Id.* Relators claim that these allegations "more than raise a strong inference that claims were submitted to Medicaid, and thus they satisfy Rule 9(b) under *Grubbs* with regard to an (a)(1) claims." *Id.*

The 4AC alleges that Solvay provided lists of ICD-9 diagnosis codes to physicians "for the sole purposes of evading formulary controls and sometimes concealing actual uses in order to obtain reimbursement for Luvox, Aceon and AndroGel." Dkt. 114 at 146. Solvay allegedly trained sales representatives to distribute the codes to practitioners, and sales representatives allegedly coached physicians to submit alternative diagnoses to government health plans. *Id.* at 147. The 4AC contains examples of physicians who used these codes when writing prescriptions for Medicaid patients. *Id.* at 148-49. These examples, however, do not indicate that the codes used by the physicians did not actually meet the patients' diagnoses. For example, the 4AC alleges that Dr. Eighty-six's sales representative provided code 440.9 to him or her, which stands for Atherosclerosis (unspecified), and that Dr. Eighty-six used the code immediately with one of his or her Medicaid

patients. *Id.* at 148. The 4AC fails, however, to allege that this diagnosis code did not match the patient's symptoms. Thus, it is unclear from the 4AC how the claim is a false claim. The 4AC also alleges that Doe's manager wrote an email indicating that the "best codes" for obtaining reimbursement for AndroGel prescriptions "are the ones that reflect the symptoms, not the disease, such as ED [erectile dysfunction], Low Libido, Depressed Mood, Fatigue/Tiredness, etc." *Id.* at 149. There is no indication, however, that a claim for a prescription for a symptom rather than the disease is a false claim. There are no allegations that any patient receiving a prescription for AndroGel for a symptom rather than a disease did not actually have the specified symptom. The 4AC also alleges that Dr. Eight-nine and Dr. Ninety "prescribed only AndroGel among testosterone products and chose [ICD-9] codes based on positive answers to the ADAM questionnaire." Dkt. 114 at 149-50. If the patients' responses were positive, then the codes apparently matched the patients' symptoms. Thus, any resulting claims could not be considered false.

Because there is no indication in the 4AC that claims arising from the ICD–9 codes Solvay allegedly provided to physicians are false claims, the 4AC fails to state a claim under subsection (a)(1) relating to ICD-9 manipulation with particularity. Accordingly, SPI's motion to dismiss the federal FCA claims relating to ICD-9 manipulation is GRANTED.

d. Subsection 3729(a)(1)(B) (2009) Claims

Relators contend that Solvay knowingly used, or caused to be made or used, false records or statements, or omitted material facts to either get false or fraudulent claims paid or approved by the government or that were material to false or fraudulent claims, in violation of section 3729(a)(2) (2006). SPI argues, in conjunction with its claims that the subsection 3729(a)(1) (2006) claims should be dismissed, that the subsection 3729(a)(2) (2006) or 3729(a)(1)(B) (2009) should be

dismissed. SPI, however, fails to differentiate between the two subsections after its initial discussion. Subsection 3729(a)(1), however, is known as the "presentment provision," and subsection 3729(a)(2) (2006)/3729(a)(1)(B) (2009) is known as the "false record or statement provision." *Grubbs*, 565 F.3d at 184. The false record or statement provision does not require a showing that the alleged false claims were presented to the government. *Id.* at 192-93 (citing *Allison Engine Co v. United States ex rel. Sanders*, 553 U.S. 662, 670, 128 S. Ct. 2123 (2008)). Subsection 3729(a)(1)(B)(2009) imposes FCA liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

In *Allison Engine Co v. United States ex rel. Sanders*, the Supreme Court of the United States interpreted subsection 3729(a)(2) (2006) as requiring that "the defendant made a false record or statement for the purpose of getting 'a false or fraudulent claim paid or approved by the government.'" 553 U.S. at 671. It additionally held that "it is insufficient for a plaintiff asserting a § 3729(a)(2) claims to show merely that '[t]he false statement's use . . . result[ed] in obtaining or getting payment or approval of the claim,' . . . or that 'government money was used to pay the false or fraudulent claim'"; instead, "a plaintiff asserting a § 3729(a)(2) claim must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." *Id.* at 665. Congress responded to the holding in *Allison Engine* by passing the Fraud Enforcement and Recovery Act of 2009 ("FERA"), which amends subsections 3729(a)(2) and 3729(a)(3) (the corresponding conspiracy subsection). Senator Leahy of the Committee on the Judiciary submitted a Senate Report on FERA, in which he noted that the bill would clarify and correct the erroneous interpretations of the FCA in *Allison Engine* and in a case decided by the District of Columbia Court of Appeals that held that FCA liability could only attach

if a claim was presented to the federal government and paid by federal grant or contract funds. *See* S. Rep. No. 111-10, at 10 (2009), 2009 WL 787872 (discussing *Allison Engine* and *United States ex rel Totten v. Bombardier Corp.*, 380 F.3d 488 (2004)). Senator Leahy noted that under *Allison Engine*, "even when a subcontractor in a large Government contract knowingly submits a false claim to a general contractor and gets paid with Government funds, there can be no liability unless the subcontractor intended to defraud the Federal Government, not just their general contractor." *Id.* Senator Leahy indicated that this interpretation was "contrary to Congress's original intent in passing the law and create[d] a new element in a FCA claim and a new defense." *Id.* The new bill removed the term "to get," which the *Allison Engine* court had interpreted as creating an intent requirement, as well as the phrase "paid or approved by the Government," and added the term "material to." *Id.* at 12. The new amendments defined "material" as "having a natural tendency to influence, or being capable of influencing, the payment or receipt of money or property." *Id.* The report notes that these changes "prevent a new 'presentment' requirement from being read into the section." *Id.*

Because Congress made the FERA amendments to subsection 3729(a)(2) (2006) (now 3729(a)(1)(B)) apply to all claims pending on June 7, 2008, and the Fifth Circuit has interpreted this to mean that it applies to lawsuits that were pending as of that date, the court must apply the amended subsection. The plain language of the amended subsection and the Congressional history indicate that the court need not consider whether Solvay made false statements with the intention of getting false claims paid by the federal government. Rather, the court must consider whether the false or fraudulent statements made by Solvay were material to a false or fraudulent claim, i.e., they had a "potential to influence the government's decisions." *Longhi*, 575 F.3d at 470; *see also United*

States ex rel. Loughren v. Unum Grp., 613 F.3d 300, 307 (1st Cir. 2010) (defining "material" for FCA claims).

The first factor the court must consider for any FCA claim is whether a false statement or fraudulent course of conduct has been alleged. *See Longhi*, 575 F.3d at 467. As described above, the 4AC sets forth details about an off-label promotion scheme for the Drugs at Issue, and it has provided sufficient particularity to satisfy Rule 9(b). The second factor is scienter—the challenged pleading must allege that the defendant had "actual knowledge of the information," was acting "in deliberate ignorance of the truth or falsity of the information," or was acting "in reckless disregard of the truth or falsity of the information." *Id.* Here, Solvay does not argue that scienter is inadequately alleged. The third factor is materiality. *Id.* Relators have alleged sufficient facts for their claims under subsection 3729(a)(2) to demonstrate that Solvay engaged in the alleged marketing schemes with the intention that these schemes would have the natural tendency to influence the decision of the government to pay the claims resulting from the schemes. They have asserted facts indicating that Solvay had an intricate scheme to market each drug for off-label uses and that Solvay targeted its off-label marketing campaigns to doctors who prescribed to Medicaid populations and other healthcare programs by, for instance, distributing lists to sales representatives of doctors who prescribed Luvox, Aceon, or AndroGel to patients within these programs, and that Solvay intentionally targeted members of state Medicaid P&T committees to gain favorable treatment of the Drugs at Issue on state Medicaid formularies.[16] *See* 4AC at 111-122. The fourth element for FCA claims, presentment, does not apply to subsection 3729(a)(2) (2006) claims. It is

[16] The court describes the allegations relating to materiality in more detail in Part II.B.3.a.ii, *infra*, which addresses SPI's specific claim, under Rule 12(b)(6), that Relators failed to plead that the claims were false or material.

unclear whether allegations that claims were actually submitted to the federal government is required under subsection 3729(a)(1)(B) (2009), but, if that element is required, it is adequately alleged for the same reasons that the presentment requirement of subsection 3729(a)(1) (2006) is adequately alleged.

Because the details in the 4AC about the allegations in the 4AC that Solvay engaged in the alleged marketing schemes with the intention that the schemes would have the natural tendency to influence the decision of the government to pay the claims resulting from the schemes, Solvay's motion to dismiss Relators' subsection 3729(a)(2) (2006)/3729(a)(1)(B) (2009) claims because they lack Rule 9(b) particularity is DENIED.

3. Rule 12(b)(6) (FCA)

a. Alleged Kickbacks

Under the AKS, 42 U.S.C. § 1320a-7b(b), it is illegal for an individual to

> knowingly and willfully . . . [receive] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(1)(A). Likewise, it is illegal to

> knowingly and willfully [offer or pay] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(A).

SPI argues that Relators' FCA claims should be dismissed under Rule 12(b)(6) for the following reasons: (1) FCA claims for violations of the AKS must be premised on a false

certification to the Government by the pharmacies submitting claims for reimbursement that SPI complied with the AKS in its dealings with the prescribing physician, and the 4AC fails to allege certification; and (2) the 4AC fails to plead falsity or materiality as to the alleged FCA violations based on off-label promotion and ICD-9 code manipulation. Dkt. 122 at 22, 26. As to the former claim, Relators claim that FCA liability does not require false certification when the goods or services for which reimbursement is sought are tainted by kickbacks because kickback-tainted claims are non-reimbursable when they are intentionally or recklessly caused to be submitted. Dkt. 131 at 22. Relators argue, however, that they have plausibly pled certification, as they have alleged that compliance with applicable laws and regulations was a condition of payment for both the federal and state FCAs. Dkt. 131 at 26-27. As to the latter claim, Relators point to allegations in the 4AC that reimbursement for off-label uses are not generally covered by Medicaid and other government health programs, and that the programs' exceptions are generally limited to medically accepted indications. Moreover, Relators contend that they have pled at least one off-label use for each drug that was promoted by Solvay yet is not reimbursable under any circumstances because it is not listed in any drug compendium and is thus not a medically accepted use. Dkt. 131 at 29. Relators also note that there are problems with the uses that were listed in DrugDex and that some of the uses that were listed in DrugDex were not actually supported by DrugDex. *Id.* at 30.

I) Certification

In order for a claim for reimbursement to be a false claim under the FCA it must be "false." SPI argues that claims for reimbursement can be either "factually false" or "legally false." Dkt. 139 at 10. SPI contends that the claims for reimbursement of the Drugs at Issue are not factually false because they are for drugs that were actually disbursed. And, SPI alleges that a claim for

reimbursement cannot be rendered "legally false" simply because it resulted from a violation of a statute. *Id.* SPI argues that Relators must, at a minimum, specify the certification that they allege makes it facially plausible that pharmacy claims were legally false. Dkt. 139 at 13. SPI additionally asserts that Relators cannot rest their claims on an implied certification theory because the Fifth Circuit has not recognized an implied certification theory. Dkt. 139 at 12.

The United States, though declining to intervene in this action, filed a statement of interest relating to this contention. Dkt. 130. The United States claims that it has "a substantial interest in the proper interpretation of the False Claims Act, which also serves as the model for many similar state anti-fraud statutes, because it is the government's primary tool to combat fraud and recover losses from fraud in federal contracts and programs," and that it "has an especially strong interest in the proper application of the FCA to claims for reimbursement for drugs prescribed because of kickbacks." *Id.* "When . . . the United States does not intervene in an FCA action, the *qui tam* plaintiff-relator is the only party who has the 'right to conduct the action.'" *United States ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 927 (5th Cir. 2007). The government, however, retains various rights including the right to be served with copies of pleadings, to limit discovery, to later intervene under certain circumstances, to settle with the defendants, and to seek dismissal of the case. *Id.* The Fifth Circuit has noted that "[t]here is nothing in the FCA that prohibits the government from submitting an *amicus curiae* brief." *Id.* Rather, the "extent to which the court permits or denies *amicus* briefing lies solely within the court's discretion." *Id.* Here, the court finds the United States' statement of interest to be timely and useful and therefore accepts the statement of interest as an amicus brief.

a) FCA Liability Based on Violations of AKS

Relators argue that nothing "in the FCA or its history suggests that 'certification,' whether express or implied, is the only form of a 'false or fraudulent' claim," and that so long as a claim is nonreimbursable, it is a false claim under the FCA. Dkt. 131 at 21-22. Relators assert that compliance with the AKS is a condition of receiving Medicare payment and claim, therefore, that "where the goods or services are tainted by kickbacks and therefore nonreimbursable, it is not necessary to examine 'false certification,' whether express or implied." *Id.* at 22. Relators contend that kickback-tainted prescriptions are inherently fraudulent and that the FCA "surely encompasses claims that are *the product of* fraudulent conduct." *Id.* at 23.

The United States likewise asserts that "claims for reimbursement for drugs prescribed *because of kickbacks* are plainly false under the FCA even in the absence of any express or implied false certification." Dkt. 130 at 2. The United States claims that "the judgment of a physician who receives something of value in return for the referral of medical procedures is *per se* tainted by the financial incentive being offered." Dkt. 130 at 8 (citing Kickbacks Among Medicaid Providers, Report of the Senate Special Committee on Aging, S. Rep. No. 95-320, at 2 (1977)). The United States and Relators cite several cases in which they claim courts have determined that claims for payment of services induced by kickbacks are false claims under the FCA. *Id.* (citing *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211, 1223 n.8 (10th Cir. 2008); *United States ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259-60 (11th Cir. 2005); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006), *aff'd* 517 F.3d 449 (7th Cir. 2008)*; United States ex rel. Jamison v. McKesson*, No. 2:08CV214-SA-DAS, 2009 WL 3176168, at *11 (N.D. Miss. Sept. 29, 2009).

The United States asserts that "the question of 'falsity' turns on whether the claimant is eligible for payment under the federal program at issue." Dkt. 130 at 8 (citing *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006)).

Additionally, the United States claims that while there is no plain language in the version of the FCA that was in effect during the time period at issue here indicating that violations of the AKS are *per se* violations of the FCA, Congress has recently clarified its position with regard to the whether kickbacks render claims "false" under the FCA in the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)). Dkt. 130. Relators likewise claim that "Congress recently confirmed" that kickback-tainted claims are "false" by enacting PPACA. Dkt. 131 at 24. The United States argues that "the PPACA amendment reflects the basic principle, already established in the 1986 FCA amendments, that 'claims may be false even though services are provided as claimed if, for example, the claimant is ineligible to participate in the program.'" Dkt. 130 at 10 (quoting Sen. Rep. No. 345, 99th Cong. 2d Sess., at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274). The United States maintains that PPACA clarified the relationship between the AKS and FCA and that the amendment is persuasive evidence of how claims prior to the effective date of the amendment should be treated. *Id.* Relators also assert that the PPACA amendment "strongly evidences Congress's intent as to the prior law." Dkt. 131 at 24.

SPI argues that the claims at issue are not "factually false" claims and that the PPACA is not necessarily a *clarification*. Rather, SPI argues that while the PPACA may make kick-back tainted claims false *after* its enactment, it has no bearing on whether kickback-tainted claims were considered false under the pre-PPACA Anti-Kickback Statute.

With the PPACA, Congress amended the Anti-Kickback Statute to provide that a "claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim" within the meaning of the FCA. 42 U.S.C.A. § 1320a-7b(g) (Supp. 2011). In discussing the bill, Senator Leahy noted that it amends "the anti-kickback statute to ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves," and he stated that the "bill clarifies the intent requirement of another key health care fraud statute in order to facilitate effective, fair, and vigorous enforcement." 155 Cong. Rec. S10852-01 (Oct. 28, 2009) (statement of Sen. Leahy), 2009 WL 3460582, at *S10854 (Westlaw). Senator Kaufman also discussed the bill, noting that efforts to prosecute violations of the Anti-Kickback Statute had been hindered because claims resulting from kickbacks were "laundered into . . . 'clean' claim[s] when an innocent third party submit[ted] the claim to the government for payment." 155 Cong. Rec. S10852-01, 2009 WL 3460582, at *S10853. Senator Kaufman stated that the bill remedied "the problem by amending the anti-kickback statute to ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves." *Id.*

This legislative history, unfortunately, does not answer the question before this court—whether the pre-PPACA statute should be interpreted as rendering a claim resulting from violations of the AKS a "false" claim under the FCA. The United States argues that the amendment is persuasive evidence of how claims made prior to the effective date of the new legislation should be treated, and the court agrees that it is *persuasive*. *See Red Lion Broad. Co. v. F.C.C.*, 395 U.S. 367, 380-81, 89 S. Ct. 1794 (1969) ("Subsequent legislation declaring the intent of an earlier statute

is entitled to great weight in statutory construction."). However, it is not definitive, and the court must also consider how courts, and particularly the Fifth Circuit, treated the pre-PPACA statute.

The United States and Relators cite several cases in support of their position that claims resulting from violations of the AKS are automatically false claims under the FCA. However, the cited cases do not provide support for the proposition that the court should consider any claims submitted as a result of Solvay's alleged kickbacks to be false claims under the FCA *absent certification* of compliance with health care laws by the entity submitting the claims. Instead, in each of these cases, the courts reasoned that *filing a certificate of compliance* with health care laws and regulations can result in FCA liability if the entity has submitted claims that resulted from violations of the AKS. *See Conner*, 543 F.3d at 1223 n.8 (noting that several other courts had reasoned that violations of the AKS rendered the certification of compliance with laws and regulations contained in an annual cost report by a hospital false, but finding it unnecessary to reach the issue); *McNutt*, 423 F.3d at 1259-60 (finding that the government, which asserted a claim that the defendant had (1) violated the AKS, (2) certified on the Medicare enrollment form that they would comply with the statute, and (3) submitted claims for reimbursement knowing they were ineligible for payments, had stated a claim under the FCA); *Schmidt*, 386 F.3d at 243 (holding that the plaintiff "alleged a violation of the FCA when he alleged that [a hospital] certified its compliance with federal health care law knowing the certification was false," as the hospital had allegedly accepted kickbacks from the defendant orthopedic implant manufacturer, and that the implant manufacturer could likewise be liable if it knew the kickbacks would result in false certifications of compliance to Medicare); *Rogan*, 459 F. Supp. 2d at 717 (noting that "falsely certifying

compliance with the AKS in a Medicare cost report is actionable under the FCA");[17] *Jamison*, 2009 WL 3176168, at *11 (noting that "[s]ubmitting false certificates of compliance with federal health care law, such as the Anti-Kickback Statute, creates False Claims Act liability"). Thus, the cases cited by the United States and Relators do not support their interpretation of the pre-PPACA statute.

Fifth Circuit caselaw likewise does not support a finding that claims arising before PPACA resulting from a violation of the AKS should be considered false without an allegation that the entities submitting the claims certified compliance with health care laws. In *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997), the Fifth Circuit reviewed a district court's order granting the defendants' motion to dismiss for failure to state a claim. The *qui tam* plaintiff, Thompson, alleged that the defendants falsely certified in annual cost reports that the Medicare services identified were provided in compliance with all laws and regulations, yet the services were rendered in violation of the AKS and the Stark laws.[18] *Thompson*, 125 F.3d at 901. The district court held that these AKS allegations were insufficient to state a claim because Thompson had not alleged that the defendants submitted false certification to obtain

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[17] The federal district court in the Northern District of Illinois stated in *Rogan* that "compliance with the [AKS] is a condition of payment by the Medicaid programs," but it made this statement in the context of discussing types of *express* certifications, and the case it cited in support of the statement also focused on certifications. *See Rogan*, 459 F. Supp. 2d at 717 (citing the pre-PPACA version of the AKS and *Barrett*, 251 F. Supp. 2d at 32 (stating that courts "have found kickback . . . violations affect the government's decision to pay" in the midst of its discussion of certification)); *cf. United States ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F. Supp. 2d 938, 947 (N.D. Ill. 2009) (noting that *Rogan* "contains a sentence to the effect that compliance with the anti-kickback statute is a condition of payment, but it does so in the context of a citation to the prohibition that applies upon a conviction for violating the statute").

[18] The Stark laws prohibit physicians from referring Medicare patients to entities providing clinical laboratory services or other designated health services if the referring physician has a nonexempt financial relationship with the entity to which he or she referred the patient. *Thompson*, 125 F.3d at 901-02 (citing 42 U.S.C. § 1395nn(a)(1), 1395nn(h)(6)).

payments for false or fraudulent claims and that Thompson failed to plead his allegations that defendants submitted claims for medically unnecessary services with particularity as required by Rule 9(b). *Id.* The Fifth Circuit noted that "claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA," as "the FCA is not an enforcement device." *Thompson*, 125 F.3d at 902. However, "where the government has conditioned a payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation." *Id.* Thompson had alleged that defendants, as a condition of their participation in the Medicare program, were required to certify that the services in their reports were provided in compliance with laws and regulations and that the defendants therefore falsely certified compliance. *See id.* One of the defendants argued that the certifications were not a prerequisite to payment of Medicare claims, and the Fifth Circuit therefore remanded the case for further factual findings on that issue. *See id.*

In light of this precedent, the court declines to hold, as the United States and Relators request, that an allegation of express certification is unnecessary and the allegations in the 4AC that claims to government entities resulted from unlawful kickbacks are sufficient to survive SPI's 12(b)(6) motion simply because the claims allegedly resulted from violations of the AKS.

b) FCA Liability Based on Violations of AKS *and* Certification

SPI argues that, since there is no allegation that it submitted false claims itself, the only way Relators can state a claim under the FCA is to show that the entities submitting the claims falsely

certified compliance with the AKS.[19] Dkt. 122 at 22-24. Relators point out that they have pled that physicians, pharmacists, and third-party payers made false certifications and represented to the government full compliance with all federal and state laws and regulations relating to fraud, including the AKS, and that compliance with these laws was a condition of payment. Dkt. 131 at 26; *see, e.g.*, Dkt. 114 ¶ 415. The 4AC additionally asserts that "'[c]ompliance with applicable Medicare, Medicaid and the various other federal and states laws . . . was an implied, and upon information and belief, expressed [sic.] condition of payment of claims.'" Dkt. 131 at 26-27 (quoting 4AC ¶¶ 441-64). Additionally, the 4AC discusses guidelines issued by the American Medical Association, the Pharmaceutical Manufacturers Association, Accreditation Council for Continuing Medical Education, and the Office of the Inspector General relating to kickbacks and asserts that the issuance of the guidelines "demonstrates that federal and state health care programs consider compliance with the Anti-Kickback Statute a prerequisite to receiving or retaining reimbursement payments from Medicaid, Medicare Part D, and other federal health care programs." Dkt. 114 at 25.

Under an express certification theory, "where the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claims when he or she falsely certifies compliance with that statute or regulation." *Thompson*, 125 F.3d at 902. Under an implied certification theory, which

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[19] SPI does not argue that the claim is only false if the entity submitting the claim knows it is false. Dkt. 139 at 16. Indeed, the Fifth Circuit has stated that "a person need not be the one who actually submitted the claim forms in order to be liable." *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004); *see also United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 389 (1st Cir. 2011) ("When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid.").

has not been adopted by the Fifth Circuit, *see United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 382 (5th Cir. 2003), "courts do not look to the supplier's actual statements; rather, the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *McKesson*, 2009 WL 3176168, at *11 (citing *Conner*, 543 F.3d at 1217-18, and *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (other citation omitted)). Thus, if a statute "*expressly* prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001).

First, the court notes that SPI's motion to dismiss asserts that the 4AC should be dismissed due to failure to sufficiently allege certification under Rule 12(b)(6), and it does so in a completely different section than its motion to dismiss for lack of particularity required by Rule 9(b). However, it argues that the 4AC has not alleged the "what when, and how of a certification case, and what made the certification a condition of compliance," and that it thus fails to state a claim under the FCA false certification theory. Dkt. 122 at 26. It is thus unclear whether SPI is suggesting that certification must be pled with particularity. However, the *Grubbs* court held that an FCA claim can survive even if it cannot allege the "details of an actually submitted false claim," so long as it does provide sufficient detail for the underlying fraudulent scheme and reliable indicia that strongly imply false claims were submitted. *Grubbs*, 565 F.3d at 190. The standard for certification should be embodied in the requirement of submission of a false claim, and the details of certification should not be required so long as there are reliable indicia that strongly imply that the certifications were made.

Relators claim that pharmacies and other entities submitting claims for payment of the allegedly false claims expressly or impliedly certified "full compliance" with the health care regulations and statutes. Caselaw suggests that at least some providers must sign a provider agreement certifying compliance with Medicare laws in order to receive reimbursement from Medicare, and the forms are standardized by the federal Centers for Medicare and Medicaid Services. *See, e.g.*, *Hutcheson*, 647 F.3d at 381-82. Thus, it is plausible that at least some providers expressly certified compliance with health care regulations and statutes and that the certifications were rendered false by unlawful kickbacks. However, the conclusory statements regarding certification in the 4AC are not reliable indicia that strongly imply that the third parties submitting the claims did, indeed, certify compliance. While it is not necessary to plead the details of the certifications of every party that allegedly submitted false claims, Relators must plead details about certifications required for reimbursement of claims from parties submitting claims for some of the alleged government health plans in order to raise the inference that other government health plans require similar certifications. Here, there are absolutely no details alleged. Accordingly, Relators have not met the pleading standard for the FCA claims premised on the AKS. SPI's motion to dismiss the claims based on kickbacks is GRANTED and the claims based on kickbacks are DISMISSED.

ii) Materiality/Falsity

In Part II.B.2.a, *supra*, the court determined that the off-label promotion allegations are sufficient to satisfy the first two prongs of the FCA test enunciated by the Fifth Circuit in *Longhi* and *Steury* with regard to a false or fraudulent statement made with the appropriate scienter. The court also determined that the alleged off-label promotion was sufficiently linked to claims for

reimbursement from government health plans for off-label uses, and thus that the fourth requirement, presentment, is met, insofar as whether *off-label* claims were submitted to the government. The third requirement for all FCA claims is materiality—the fraudulent action must have had a natural tendency to influence the government's decision regarding payment of claims. *Longhi*, 575 F.3d at 470. SPI moves to dismiss the 4AC under Rule 12(b)(6) because it fails to plead falsity or materiality as to the alleged FCA violations based on off-label promotion and ICD-9 code manipulation. Dkt. 122 at 22, 26.

First, the court notes that it found above that the claims based on ICD-9 code manipulation were not stated with particularity under Rule 9(b) because there were no reliable indicia that claims were actually submitted with ICD-9 codes that were improper for a patient's diagnosis. *See* Part II.D, *supra*. This means that the claims were not material, so there is not need to address materiality in this section. Conversely, the court found above that the alleged off-label promotion was material to off-label claims, under subsection 3729(a)(1) (2006), insofar as that requirement is encompassed in the *Grubbs* standard, *see* Part II.B.2.a, *supra*, and under subsection 3729(a)(1)(B), *see* Part II.B.2.d, *supra*.

SPI's argument here, though, is not that the alleged scheme was not material to off-label claims. Rather, SPI argues that Relators fail to allege facts demonstrating that off-label claims stemming from the alleged off-label promotion were non-reimbursable, and therefore false, claims. Dkt. 139 at 17. SPI asserts that claims for off-label uses could be reimbursable if certain state Medicaid agencies decided not to restrict off-label use or if the off-label use is included in DrugDex or other compendia, making it a "medically accepted" use. Dkt. 122 at 27-28. SPI thus contends that the government's decision regarding payment of claims would not be impacted by knowledge

that the claims were for *off-label* uses unless the claims were not for *medically accepted* uses, and most of the off-label uses alleged are medically accepted. SPI contends that Relators have not provided any details about states that would have placed restrictions on medically accepted uses.

Relators point out that the 4AC states that reimbursement for claims for off-label uses, whether arising from off-label marketing or ICD-9 code manipulation, are generally not covered by Medicaid and other health programs and that the programs' exceptions are generally limited to "medically accepted indications." Dkt. 131 at 27-28. Relators claim that details about which states cover which uses is beyond what even Rule 9(b) requires and that it is "patently unreasonable" to demand these details—particularly at the motion to dismiss stage. Dkt. 131 at 28-29. Moreover, Relators assert that the 4AC does provide particular allegations with regard to the reimbursability of the uses at issue, as it alleges at least one use that is not reimbursable under any circumstances because it is not "medically accepted." *Id.* at 29. Relators also point to allegations in the 4AC about various alleged problems with DrugDex entries for certain uses of the three drugs at issue. *Id.* Relators thus argue that (1) they have pled that each of the Drugs at Issue was promoted off label for uses that were not listed in DrugDex and thus were not medically accepted; (2) they have pled that Solvay inappropriately influenced which drugs were deemed medically accepted by influencing DrugDex entries and inappropriately influencing which drugs required prior authorization by targeting physicians on state P&T committees; and (3) it is unreasonable to require it to list which uses each state deems are not reimbursable.

The 4AC alleges that Solvay promoted each of the Drugs at Issue for uses that were not on the drugs' labels *and* not listed or not supported by DrugDex. However, while the 4AC has linked off-label promotion of the Drugs at Issue to off-label claims submitted to government health plans,

it does not link the uses that are not in DrugDex to claims submitted to government health plans. "FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the [Food, Drug, & Cosmetic Act], that are independent of any false claim." *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 702, 727 (1st Cir. 2007), *overruled on other grounds by Allison Engine*, 553 U.S. 662. Even though the 4AC clearly states that the alleged uses of Luvox, Aceon, and AndroGel are off-label, a claim for reimbursement of an off-label prescription is not automatically a "false" claim because an off-label use is not always a "medically unnecessary" use. *See Bennett v. Boston Scientific*, No. H-07-2467, 2011 WL 1231577, at *3 (S.D. Tex. Mar. 31, 2011) (Rosenthal, J.) (collecting cases) ("Courts recognize that off-label use of a drug or medical device is not the same as medically unnecessary use of that drug or device."). If an off-label use is supported by DRUGDEX or another approved compendia, then it is a "medically accepted indication," and claims for payment of medically accepted indications are not false claims. *See* 42 U.S.C. § 1396r-8d.

For example, in *Rost*, DRUGDEX stated that the FDA had not approved the drug at issue, Genotropin (also known as Somatropin), for short stature but that the drug was possibly effective for adults with short stature and its use for children with short stature was controversial. *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 14 (D. Mass. 2008) (remand after 507 F.3d 702). The *Rost* defendants argued that this listing in DRUGDEX meant that the drug's use for short stature was a medically accepted indication because it was supported by DRUGDEX. *Id.* The *Rost* court noted that there were conflicting viewpoints on whether a listing in DRUGDEX for a specific use is "support" for that use or whether the listing actually has to be positive in order to "support" the use. *Id.* (comparing *Edmonds v. Levine*, 417 F. Supp. 2d 1323 (S.D. Fla. 2006) (holding that a drug

is "supported" by citation in a compendia even if it is only "possibly effective" or even "ineffective") with Ctr. for Medicaid and State Operations, Medicaid Drug Rebate Program Release No. 141, For State Medicaid Directors: Compendia Clarification (distinguishing between "supported" and merely "listed")). The *Rost* district court ultimately determined that the record was insufficient to determine whether the citations in DRUGDEX for short stature supported the off-label use. *Id.* at 16.

Here, Relators list several problems with the DRUGDEX listings for Luvox, Aceon, and AndroGel and thus maintain that claims for reimbursement for prescriptions for the off-label uses it describes in the 4AC, even if the uses were listed in DRUGDEX, were false claims.

a) Luvox. According to Relators, at some point between 1996 and 2003, DRUGDEX listed 27 uses for Luvox, including depression, Asperger's disorder, autistic disorder, body dysmorphic disorder, compulsive buying, depression with anxiety disorder, irritable bowel syndrome, kleptomania, pathological gambling, posttraumatic stress disorder, premenstrual dysphoric disorder, stereotypic behavior, and trichotillomania. Dkt. 114 at 48. By 2008, DRUGDEX had delisted some of these uses, changed the listings for most of the OC Spectrum uses, including listings for PTSD, autism, body dysmorphic disorder, and eating disorders, from "effective" to "inconclusive" or "possibly effective," and changed the depression support from its most supportive category to a middle range category. *Id.* at 48-49. The 4AC asserts that the listings generally cite only a case study of a few subjects or, at times, only anecdotal evidence of effectiveness. Dkt. 114 at 48-49. And, the 4AC states that the FDA has specifically rejected the new drug application for the use of Luvox to treat depression twice, and the 4AC thus contends that the listing in DRUGDEX "cannot render it a 'medically accepted indication.'" Dkt. 114 at 49. The

4AC also points out that many of the studies listed in DRUGDEX in connection with off-label uses of Luvox are sponsored by Solvay or Solvay-owned subsidiaries or authored by Solvay national speakers. *Id.*

Notwithstanding the alleged problems with DRUGDEX's listed off-label uses for Luvox, according to the Medicaid statute, if the uses are "supported by one or more citations" in DRUGDEX, the uses are "medically accepted indications." 42 U.S.C. § 1396r-8(k)(6). Absent special circumstances, states cannot restrict coverage of a drug if it is used for a medically accepted indication. *See* 42 U.S.C. § 1396r-8(d)(B)(I). Many of the off-label conditions for which Relators claim Solvay promoted Luvox were supported by DRUGDEX. There can be no claim that depression, for instance, was merely listed, when Relators themselves confirm that it was in the most supportive category for some of the relevant time period. Allegations that indicate that claims were submitted for Luvox prescriptions for conditions supported by DRUGDEX do not reliably indicate that *false* claims were submitted.

The 4AC, however, asserts that Solvay promoted Luvox for uses that were not even listed in DRUGDEX, including "use as a sleep aid, all children's prescriptions outside of OCD, and the following OC Spectrum disorders: stand alone anxiety disorder, Tourette's syndrome, anti-social personality disorder, schizo-obsessive disorder, sexual compulsions, and ADHD." Dkt. 114 at 48-49. Additionally, the 4AC claims that hypochondriasis appeared only after 2003 and that Solvay had already pulled Luvox from the market at this time. *Id.* at 49.

According to the 4AC there were at least $6 million in Medicaid claims for Luvox in Texas alone and the majority of these sales were for indications other than OCD. *Id.* at 50. The specific call notes discussed in the 4AC with regard to Luvox indicate that doctors prescribed Luvox for

ADHD, infantile autism and panic disorder, or childhood psychosis after either receiving pitches from Solvay sales representatives for Luvox's use for panic disorder, autism, or the OC Spectrum, or after attending a presentation about the use of Luvox in children with anxiety, and that the prescriptions were filled. *Id.* at 50. Since use in children, other than for OCD, was allegedly never listed in DRUGDEX, these examples are reliable indicia that claims that were not eligible for reimbursement—in states that restrict access to uses of drugs that are not medically accepted[20]—were actually submitted.

b) AndroGel. With regard to AndroGel, the 4AC states that "[m]any of the off-label uses for AndroGel promoted by Solvay have not been listed in DRUGDEX and thus are not even arguably 'medically accepted,' such as andropause, diabetes, metabolic syndrome, and methadone/pain." *Id.* at 89. Additionally, it notes that weight gain in HIV patients was "delisted between 2003 and 2008" due to alleged "concerns about the listing." *Id.* at 89. It states that depression was downgraded to a middle category between 2003 and 2008, and it notes that the only citation for the use of AndroGel for depression listed in the 2003 edition was a study by a Solvay Luvox speaker. *Id.* at 90. Additionally, the 4AC indicates that the studies listed in support of the listings for the use of AndroGel for sexual dysfunction and a third of the citations for osteoporosis were either Solvay-sponsored or authored by Solvay national speakers. The 4AC states that these "conflicts of interest were not disclosed to DRUGDEX and/or do not appear on the faces of the authorities." *Id.* at 90. The 4AC also claims that even though certain uses, such as for menopause,

[20] It is clear from the 4AC that Texas restricts access to certain drugs, as it alleges that "Aceon lost its preferred Medicaid status in Texas in 2004," AndroGel was on the preferred drug list in Texas, and Texas ADAP supplemental HIV program does not cover AndroGel. Dkt. 114 at 113-14.

anxiety, and female osteoporosis, are listed in DRUGDEX, the listings are not supportive of use for these conditions due to the "conclusions of the research or its paucity." *Id.*

The specific examples of off-label prescriptions for AndroGel in the 4AC indicate that physicians prescribed AndroGel for off-label uses after receiving detailing for those uses from Solvay sales personnel. *See, e.g., id.* at 91-92 (providing details about promotions to specific doctors for off-label uses); *id.* 93-94 (providing details of specific Medicaid prescriptions for off-label uses). However, the 4AC does not provide any specific details of off-label prescriptions for uses not listed by DRUGDEX (i.e. andropause, diabetes, metabolic syndrome, and methadone/pain).[21] The AndroGel prescription examples include prescriptions for pediatric use, use in women, HIV patients, andropause and supposedly related ailments like osteoporosis and sexual dysfunction, and depression. *Id.* at 91-94 & Exhs. 71-77. The 4AC does not provide any information about the DRUGDEX listings for pediatric use. With regard to use in women, while perhaps not approved by the FDA, DRUGDEX lists AndroGel for menopause in the 2003 edition and for postmenopausal hormone replacement therapy in the 2008 edition. *Id.* at 90. The 2008 edition's listing, however, states that AndroGel's use in hormone replacement therapy has negative

[21] While Relators contend that Solvay marketed AndroGel for "andropause," a condition not listed in DRUGDEX, the actual prescriptions allegedly resulting from the andropause marketing are for "supposedly related ailments such as osteoporosis, sexual dysfunction (as a Viagra substitute), and depression." Dkt. 114 at 92. With the exception of osteoporosis, Relators do not indicate that the related ailments are not listed in DRUGDEX as conditions for which AndroGel may be prescribed. With regard to osteoporosis, Relators contend that DRUGDEX listed AndroGel as being "ineffective" for *female* osteoporosis and that the studies supporting osteoporosis, in general, were Solvay-sponsored. Regardless, there is support in DRUGDEX for, at least, use for osteoporosis for *male* patients. The data provided by Relators relating to osteoporosis prescriptions indicates that the diagnosis was for "osteoporosis, unspecified." *Id.* at 94. The genders of the four patients listed are not specified. *See id.* Thus, the court cannot deem this as reliable indicia that false claims were submitted.

effects "but is beneficial in terms of sexual function." *Id.* These listings clearly support the use of AndroGel for women in certain situations. With regard to HIV, the 4AC notes that AndroGel was delisted between 2003 and 2008 due to concerns about the listing, but the prescription examples provided are after 2003 and before 2008, a time during which the use of AndroGel in HIV patients was supported by DRUGDEX. *Id.* at 89. And, with the exception of osteoporosis in women, the conditions related to "andropause"—depression and sexual dysfunction—are supported by DRUGDEX. Relators contend that depression was downgraded to the middle category, with efficacy rated as "inconclusive," between 2003 and 2008, but the provided examples are all before 2008. *Id.* at 90. While Relators contend that the only study listed as supportive of use for depression is a study by a Solvay speaker, which Relators contend is a conflict of interest, that does not change the dispositive fact that the use was supported by DRUGDEX at the time the prescriptions were written. *See id.* Relators also contend that the studies listed that supported AndroGel's use in patients with sexual dysfunction were "largely sponsored by Solvay, or authored by Solvay speakers," and that the conflict of interest was not disclosed to DRUGDEX and does not appear on the face of the authorities. *Id.* at 90. Again, even if there was a problem with the studies listed to support the use of AndroGel in DRUGDEX, if the listing indicated that it was appropriate to use AndroGel for sexual dysfunction, then DRUGDEX supported that use. Finally, with regard to osteoporosis, 4AC contends that DRUGDEX listed AndroGel as being "ineffective" for *female* osteoporosis and that the studies supporting osteoporosis, in general, were Solvay-sponsored. *Id.* Again, the source of the studies is irrelevant so long as the substance of the listing supports the use, and there is no indication that DRUGDEX does not support use for osteoporosis for *male* patients. The prescription data provided by Relators relating to osteoporosis prescriptions indicates that the

diagnosis was for "osteoporosis, unspecified." *Id.* at 94. The genders of the patients listed are not specified. *See id.* In order to satisfy the requirements of Rule 9(b), Relators must provide reliable indicia that false claims were actually submitted. Since there is not way to tell if any of the patients who received AndroGel for osteoporosis were women, there are no reliable indicia that the prescriptions were not for a medically accepted use—osteoporosis in men. Thus, even though Relators have alleged particular details of a scheme to submit off-label claims for AndroGel paired with reliable indicia that lead to a strong inference off-label claims were actually submitted, there is not reliable indicia leading to a strong inference that *false* claims, i.e. claims that were not for a medically accepted indication under the statute, were submitted for AndroGel.

c) Aceon. The 4AC alleges that the DRUGDEX lists the following off-label uses of Aceon: hypertension–diabetes, nephropathy–diabetic, prevention of secondary stroke, and atheroscleosis (hardening of the arteries). Dkt. 114 at 62. The 4AC states that the 2003 edition of DrugDex listed Aceon as being effective for hypertension associated with diabetes, but it notes that most of the research supporting this entry is Solvay-sponsored and that the listing was downgraded to the middle category in the 2008 edition. *Id.* The 4AC states that the studies supporting the nephropathy associated with diabetes entry do not even involve Aceon—they involve other ACE inhibitors. *Id.* The only research supporting secondary stroke, according to the 4AC, is the "unsupportive PROGRESS study" and a 1996 Solvay-sponsored study. *Id.* The secondary stroke listing was downgraded from the most supportive to the middle category for the 2008 edition. *Id.* Even though the alleged support for these three listings is suspect, the DrugDex categories for the three uses support the uses.

The fourth listing, atherosclerosis, is offered because one of the biggest off-label campaigns for Aceon was allegedly "arterial wall compliance," which is not listed in DrugDex, and the 4AC posits that atherosclerosis could be understood to cover this use.[22] The listing in the 2003 edition of DrugDex for atherosclerosis, however, is "ineffective," and the condition is not listed at all in the 2008 edition. *Id.* DrugDex, thus, does not support the use of Aceon for atherosclerosis, and it therefore cannot be deemed a "medically accepted use." The examples provided by the 4AC, however, do not link the off-label promotion campaign for arterial wall compliance to prescriptions for arterial wall compliance or atherosclerosis. While the court concluded above that the fact that physicians began prescribing substantial amounts of Aceon after receiving off-label messages about arterial wall compliance is reliable indicia that it resulted in *claims* being submitted, the specific examples in the 4AC does not support the conclusion that the off-label promotion of AndroGel and Aceon resulted in materially *false* claims.

d) Alternative Ways of Showing Falsity/Materiality

Linking the off-label promotion to materially false claims with claims data is not the only way in which the 4AC could allege that the prescriptions resulting from the off-label promotion had a natural tendency to influence the government's decision regarding payment of claims. Relators argue that problems associated with the DrugDex support of the off-label uses and Solvay's specific targeting of P&T committee members to gain favorable treatment on state formularies demonstrate

[22] Exhibit 20 to the 4AC indicates that, in order to "to help Aceon pass through the more restrictive managed care programs," sales representatives could suggest that physicians use two ICD-9 codes for atherosclerosis since Aceon did not have an indication for arterial wall compliance. Dkt. 114, Exh. 20.

that the off-label promotion campaign had a natural tendency to influence the government's decision regarding payment of claims.

With regard to DrugDex, the 4AC alleges that Solvay improperly influenced what uses were included in DrugDex by manufacturing "medical literature over which it maintained control in order to submit to compendia and win access to Medicaid formulary coverage." Dkt. 114 at 108-09. This allegation includes claims of ghostwriting, conflicts of interest, and scientifically flawed studies. *Id.* at 109. The 4AC provides a specific example of a physician who was one of Solvay's "thought leaders" and has recently been exposed (in relation to other companies) as signing ghost-written articles. *Id*. The 4AC also alleges that Solvay did not disclose to DrugDex that it had financial ties to various entities that sponsored studies supporting off-label uses in DrugDex. *Id.* at 111. It is unclear to what extent the alleged problems with the support for off-label indications in the 4AC would have impacted DrugDex's decision to support the off-label uses. If DrugDex would have decided not to support the uses because the alleged problems with the studies supporting the uses, then states would not be required to reimburse for the uses. *See* 42 U.S.C. § 1396r-8(d)(1)(B)(I) (allowing states to restrict use if a drug is not prescribed for a medically accepted indication); *id.* § 1396r-8(k)(6) (defining "medically accepted indication" as a "use for a covered outpatient drug which is approved under the [FDCA] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described" in the Medicaid statute). The complaint alleges that Solvay intentionally misled DrugDex about the off-label uses and/or colluded with *Solvay* when it supported the off-label uses. Dkt. 114 at 108.

The 4AC additionally alleges that Solvay specifically geared its off-label promotion towards members of state P&T committees in a attempt to influence which drugs were included on the states'

Medicaid formularies. Dkt. 114 at 116. The 4AC alleges that "[w]ooing P&T committee members was discussed openly and earnestly on periodic conference calls with upper management." *Id.* at 117. A Solvay sales representative allegedly argued for the inclusion of Aceon on the Preferred Drug List in a meeting with the West Virginia P&T Committee. *Id.* at 118. She allegedly relied on the PROGRESS study, which the 4AC alleges does not support the use of Aceon at all. *See id.*

Taken together, the allegations about problems with the DrugDex listings and the alleged wooing of P&T committee members plausibly influenced which drugs were placed on state formularies and thus had a natural tendency to influence the states' decision, and in turn the federal government's, decision with regard to payment. Accordingly, the 4AC plausibly satisfies the materiality element.

SPI additionally asserts that claims for off-label uses could be reimbursable if certain state Medicaid agencies decided not to restrict off-label use and contends that Relators have not provided any details about states that would have placed restrictions on medically accepted uses. Relators argue that it is patently unreasonable to require them to do so. The court agrees that this level of detail is not necessary at the pleading stage. *Cf. Grubbs*, 565 F.3d at 190 (stating, in the context of holding that exact contents of bills were not required to state a claim, that "[t]o require these details at pleading is one small step shy of requiring actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates").

In sum, the court finds that the 4AC plausibly pleads that the claims resulting from off-label promotion were false or material. SPI's motion to dismiss the off-label claims based on the alleged lack of falsity or materiality is DENIED.

C. Count III: Federal FCA Conspiracy

Relators allege that Solvay conspired with physicians to promote of-label uses of the Drugs at Issue and to pay kickbacks to physicians in violation of the AKS and subsection 3729(a)(3) (2006) of the FCA. Dkt. 114 at 169. Congress did not make the FERA amendments to subsection 3729(a)(3), which it amended and recodified as subsection 3729(a)(1)(c), retroactive. The amended version applies only to "conduct on or after the date of enactment"—May 20, 2009. The court therefore will analyze the FCA conspiracy claims in accordance with the text of the previous version and the caselaw interpreting that version. The previous version states: "Any person who . . . conspires to defraud the Government by getting a false or fraudulent claim allowed or paid[,] . . . is liable to the United States Government . . . ."

SPI contends that Relators' conspiracy claims fail under Rules 9(b) and 12(b)(6) for the same reasons the underlying claim fails and, additionally, because Relators fail to allege the basic elements of a conspiracy. Dkt. 122 at 29. Like the underlying claims, a conspiracy claim under section 3729(a)(3) (2006) must be plead with particularity under Federal Rule of Civil Procedure 9(b). *Grubbs*, 565 F.3d at 193. Thus, like with the underlying claims, the motion to dismiss the conspiracy claims based on off-label promotion is DENIED, the motion to dismiss the conspiracy claims based on ICD-9 code manipulation is GRANTED, and the motion to dismiss the conspiracy claims based on the AKS is GRANTED.

In addition, to plausibly plead an FCA conspiracy claim, Relators must allege "'(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by [the Government] and (2) at least one act performed in furtherance of that agreement.'" *Grubbs*, 565 F.3d at 193 (quoting *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343

(5th Cir. 2008)). The actual presentment of a false claim is not necessary. *See id.* Relators claim that the following allegations in the 4AC assert an agreement and an act or acts in furtherance of that agreement: (1) Solvay allegedly paid doctors' airfare and lodging to go to a luxury hotel or resort to participate in marketing feedback panels about Aceon and Luvox, during which the physicians, deemed "consultants," would provide comments about the presented marketing schemes, Dkt. 114 at 126; (2) Solvay allegedly would provide physicians with honoraria or fees for participating in regional advisory boards during which off-label indications for AndroGel and Luvox would be discussed, *id.* at 126-27; (3) Solvay allegedly provided honoraria and other kickbacks to physicians who prescribed Aceon and provided case studies about its use for secondary stroke patients, *id.* at 129 & Exh. 114; (4) Solvay allegedly paid physicians participating in the ACES program, who signed district advisory board agreements and completed patient tracking forms, $100 for each patient to whom they prescribed Aceon, *id.* at 136; and (5) Solvay allegedly paid physicians, who signed expert interview consultants' request forms, $100 after the launch of Aceon for participating in an interview about the physicians' treatment of hypertension prior to the launch of Aceon, *id.* at 135.

In order to state a claim, these alleged facts must give rise to an inference that the Solvay and the physicians conspired to defraud the government. *Allison Engine*, 553 U.S. at 672. Moreover, if the alleged conduct pertains to an agreement to make a false record or statement (subsection 3729(a)(2) (2006)), "it must be shown that the conspirators had the purpose of 'getting' the false record or statement to bring about the Government's payment of a false or fraudulent claim." *Id.* at 672-72. In other words, "it must be established that [the alleged conspirators] agreed that the false

record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim." *Id.* at 673.

Here, there is no allegation that the physicians made any agreement with the purpose of having an impact on the Government's decision to pay false or fraudulent claims. For example, in an agreement relating to receiving money for submitting case studies about patients with secondary stroke in exchange for $150, the document specifically states that Solvay was "interested in collecting cases [for a newsletter] that illustrate the prevention of secondary stroke." Dkt. 114, Exh. 114. While this would qualify as an agreement to help promote an off-label use of Aceon, it does not indicate in any way that the newsletter would be used to influence physicians who prescribe to patients on government health plans to prescribe the drug off-label. While the physicians entering into this agreement could certainly infer that some physicians prescribing to some patients on government health plans may receive the newsletter, this inference is too far removed from the agreement to state a claim for a conspiracy to defraud the government. The letter recruiting physicians to participate in the ACES consultation program also demonstrates that whatever agreement the physician entered into with Solvay was not related to defrauding the government. *See* Dkt. 114, Exh. 125. The letter states that the purpose of the program is to enable physicians to observe "patient product results outside of clinical trial settings to more accurately demonstrate local outcomes." *Id.* There is no mention of Medicaid or any government health programs. The details of the alleged conspiracy and agreements that are attached to the 4AC simply do not state with particularity that physicians agreed to be part of a scheme to defraud the government. Accordingly, to the extent the conspiracy claims are not dismissed on other grounds, Solvay's motion to dismiss the conspiracy count is GRANTED.

D. Count IV: Federal FCA Retaliation

Fourth, SPI contends that the retaliation claims should be dismissed because the applicable limitations period is, at most, 180 days, yet King did not file his claim for over a year after the alleged retaliation against him, and Doe did not file her claim until approximately eight months after the alleged retaliation against her. Dkt. 122 at 31. Relators argue that the 180-day limitations period would frustrate the FCA's provisions and the court should apply either a two-year statute of limitations from a Georgia statute that is analogous to the FCA or the two-year statute of limitations contained in section 16.003 of the Texas Civil Practices and Remedies Code. Dkt. 131 at 41-42.

In *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, the United States Supreme Court ruled that the six-year statute of limitations applying to FCA claims, in general, does not apply to FCA *retaliation* claims. 545 U.S. 409, 422, 125 S. Ct. 2444 (2005). Rather, the "most closely analogous state statute of limitations . . . applies." *Id.* The United States Supreme Court specifically noted which state statutes were likely the most closely analogous for several states, and, for Texas, it cited section 16.003 of the Texas Civil Practices and Remedies Code, which governs personal injuries, and section 554.005 of the Texas Government Code, which governs retaliation actions for whistle-blowers. *Id.* at 419 & n.3.

Relators argue that the court must apply the most closely analogous statute of limitations of either Georgia, where the cause of action allegedly accrued, or Texas, where this case is pending, and they claim that the Supreme Court has not addressed which state to choose when the alleged retaliation took place outside of the forum state. Dkt. 131 at 41-42 & n.32. SPI agrees that the court must apply the most closely analogous state statute, but it claims, citing a case relating to which statute of limitations to use for 42 U.S.C. § 1983 claims, that the court should chose the forum state.

Dkt. 139 at 21 (citing *Cruz v. Louisiana ex rel. Dept. of Pub. Safety & Corr.*, 528 F.3d 375, 379 (5th Cir. 2008). Relators argue that the case SPI cites is irrelevant because the forum state and the *lex loci* were both in Louisiana. Dkt. 140-1 at 16 (discussing *Cruz*, 528 F.3d at 378)).

The court finds that it should apply the law of Texas, the forum state. The court would not apply Georgia substantive law if the retaliation cause of action accrued in Georgia, because the FCA is, of course, a federal statute. The court would not apply Georgia procedural law to this case because federal courts apply federal procedural law. *See All Plaintiffs v. All Defendants*, 645 F.3d 329, 335 (5th Cir. 2011). Thus, it does not make sense to borrow Georgia's statute of limitations.

Since the court has decided to apply the most analogous Texas statute, it must determine which statute is most analogous. The FCA retaliation statute states: "Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment . . . because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section . . . shall be entitled to all relief necessary to make the employee whole."[23] 31 U.S.C. § 3730(h) (2006). Relators argue that, if the court were to rely on Texas law, it should apply the two-year statute of limitations for personal injury claims, which is specifically mentioned by the Supreme Court in *Graham*. Dkt. 131 at 42. However, the Supreme Court also mentions the whistleblower statute, which has a 90 day statute of limitations. *Graham*, 545 U.S. at 419 n.3 (citing both Tex. Gov't Code § 554.005 and Tex. Civ. Prac. & Rem. Code § 16.003 as potential analogous statutes); Tex. Gov't Code Ann. § 554.005 (Vernon 2002). SPI additionally suggests that the Texas healthcare whistleblower statute is most

[23] This subsection was amended in 2009 and 2010, but Congress did not make the amendments retroactive. *See* 31 U.S.C.A. § 3730 note (Supp. 2011).

closely analogous to the FCA retaliation claim; the statute of limitation for the healthcare whistleblower statute is 180 days. *See* Dkts. 122, 139; Tex. Health & Safety Code Ann. § 161.134(h) (Vernon 2002).

This court, joining its sister court in *United States ex rel. Smart v. Christus Health* and the federal district court in the Northern District of Texas in *United States ex rel. Wall v. Vista Hospice Care, Inc.*, will apply the 180 day statute of limitations contained in the Texas healthcare whistleblower statute. *See United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709 (N.D. Tex. 2011) (applying the 180 day statute of limitation in the Texas hospital whistleblower's retaliation action in an FCA retaliation case and noting that the case would have the same result if the court were to apply the 90 day statute of limitations); *United States ex rel. Smart v. Christus Health*, 626 F. Supp. 2d 647, 657 (S.D. Tex. 2009) (Rainey, J.) (applying the 180 day statute of limitations in Texas Health & Safety Code § 161.134(h) to an FCA retaliation claim). The personal injury statute of limitations applies to trespass, conversion, taking or detaining personal property of others, forcible entry and detainer, forcible detainer, and personal injury resulting in death. Tex. Civ. Prac. & Rem. Code Ann. § 16.003 (Vernon 2002). None of these causes of action relates in any way to a retaliation claim. The whistleblower statute with the 90-day statute of limitations, on the other hand, is directly on point as evidenced by the title of the chapter in which it is contained: "Protection for Reporting Violations of Law." *See* Tex. Gov't Code Ann. § 554.005. Under this statute, a "state or local governmental entity may not suspend or terminate the employment of . . . a public employee who in good faith reports a violation of law." *Id.* § 554.002(a). The title of the healthcare whistleblower statute, which has a statute of limitations of 180 days, is also directly on point: "Retaliation Against Employees Prohibited." *See* Tex. Health

& Safety Code Ann. § 161.134. This statute states that a "hospital, mental health facility, or treatment facility may not suspend or terminate the employment of . . . an employee for reporting to the employee's supervisor, . . . a violation of law." *Id.* § 161.134(a). Since the instant case involves alleged healthcare fraud and does not involve public employees, the healthcare whistleblower statute is the most closely analogous.

Under the 180 day statute of limitations, both King's and Doe's retaliation claims are untimely. Since an amendment to the complaint will not cure this deficiency, SPI's motion to dismiss the retaliation claims is GRANTED, and the retaliation claims under the FCA are DISMISSED WITH PREJUDICE. Since the claims are time-barred, the court finds it unnecessary to address SPI's argument that Relators have not pled facts demonstrating that King and Doe engaged in protected activity.

E. Counts V-XXXIII: Local *Qui Tam* Claims

SPI contends that Relators' state and local *qui tam* claims should be dismissed for the same reasons the federal claims should be dismissed or, alternatively, if the court dismisses the federal claims, the court should decline to exercise pendant jurisdiction over the state claims. Dkt. 112 at 34. Since the court has not dismissed all of the federal FCA claims, it declines to dismiss the state of local claims on either of these theories. SPI, however, also asserts that each state claim is flawed for other reasons, which the court will address in turn. Dkt. 122 at 34.

1. City of Chicago (Count 33)

Before reaching the contested issues, the court notes that Relators concede that their claims on behalf of the City of Chicago (Count 33) should be dismissed. Dkt. 140-1 at 17. Thus, SPI's

motion to dismiss the claims based on the Chicago FCA is GRANTED, and Relators' claims on behalf of the City of Chicago (Count 33) are DISMISSED WITH PREJUDICE.

2. Delaware and New Mexico (Counts 10 and 22)

SPI moves to dismiss Relators' claims made under the Delaware and New Mexico FCAs (Counts 10 and 22, respectively), arguing that the Delaware and New Mexico FCAs permit a relator to continue a *qui tam* action in which the state does not intervene only if the appropriate authorities in those states issue a written determination that there is substantial evidence that a violation occurred. Dkt. 122 at 35-36. Under New Mexico Statute section 27-14-7(E)(2) (2004) (hereinafter, the "N.M. Substantial Evidence Section"), the New Mexico Government is required to either proceed with an FCA action filed by a *qui tam* relator or "notify the court and the person who brought the action that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action if the department determined that there is substantial evidence that a violation of the Medicaid False Claims Act has occurred." Similarly, under Delaware Code title 6, section 1203(b)(4)(B) (2000) (hereinafter, the "Del. Substantial Evidence Section"), the Delaware Government is required to either elect to proceed with the action or notify "the court that it declines to take over the action, in which case the private party bringing the action shall have the right to conduct the action if, pursuant to paragraph (2) of this subsection, the [Delaware] Attorney General determined that there is substantial evidence that a violation of this chapter has occurred." Relators first contend that neither New Mexico nor Delaware has declined to intervene. Dkt. 131 at 36. However, on November 20, 2009, while this case was still under seal, the State of Texas filed a notice of non-intervention on behalf of several different states, including New Mexico and Delaware. Dkt. 50.

Relators next argue that the Delaware Substantial Evidence Section no longer applies because the Delaware General Assembly amended this section in 2009, and the new provision simply requires the Delaware Department of Justice to either proceed with the action or notify the court that it declines, "in which case the private party bringing the action shall have the right to conduct the action." Del. Code tit. 6, § 1203(b)(3)(b) (2009). The amended statute, however, does not apply retroactively. *See United States ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. RDB 07-3176, 2010 WL 2733321, at *6 (D. Md. Jul. 9, 2010) (noting that under Delaware law, "retroactivity is a matter of legislative intent" and that Delaware courts will not infer such intent, and then dismissing a Delaware FCA *qui tam* action under the previous version of the statute). Thus, the court will apply the previous version of the Delaware statute.

There is no contention that the Delaware Attorney General determined that there was substantial evidence that a violation of Delaware's FCA occurred. However, SPI has failed to explain how dismissal under Rule 12(b)(6) is appropriate. The Substantial Evidence Section does not state that the Delaware Attorney General must notify the *court* of its determination regarding substantial evidence, and Relators are not required on a Rule 12(b)(6) motion to come forward with evidence. Relators could not have alleged in their complaint that the Delaware government had issued such a notice since the statute does not require such a notification until after the complaint is filed. SPI's motion to dismiss the Delaware False Claims and Reporting Act claim (Count 10) because the Delaware Attorney General has failed to provide notice that the Relators may proceed is DENIED.

Relators make no arguments with regard to SPI's argument that Relators cannot maintain a claim under the New Mexico FCA unless the State intervenes or provides them with a statement of

substantial evidence, with the exception of their erroneous argument that New Mexico has not declined to intervene. However, since, as with the Delaware statute, SPI has not explained how dismissal under this section is appropriate under Rule 12(b)(6), SPI's motion to dismiss the New Mexico FCA claim (Count 22) as it relates to the alleged absence of a substantial evidence statement from New Mexico is DENIED.

SPI alternatively argues that the New Mexico FCA (§ 27-14-1 *et seq.*) only permits an "affected person" to bring a civil action, and that neither King, who is a resident of Virginia, nor Doe, who is a resident of Florida, could be affected by the New Mexico statute.[24] *See* N.M. Stat. Ann. 1978, § 27-14-7(B). SPI contends that since the term "affected person" is not defined in the statute, under New Mexico law, must be given its "common and ordinary meaning." Dkt. 122 at 35 (citing *Albuquerque Bernalillo Co. Water Util. Auth. v. NMPRC*, 2010-NMSC-013, 148 N.M. 21, 229 P.3d 494, 519 (turning to the dictionary to find the "common and ordinary meaning" of the phrase "periodically fluctuate")). Relators argue, however, that the court should apply the meaning of "affected person" from the *Delaware* False Claims and Reporting Act, which defines "affected person" as including employees and former employees of an entity liable under the Delaware False Claims and Reporting Act.[25] 6 Del. Code § 1202(1) (2000). This is an extremely broad definition

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[24] Count 22 of the 4AC asserts claims under both the New Mexico Medicaid FCA (§ 27-14-1 *et seq.*) and the New Mexico Fraud Against Taxpayers Act (§ 44-9-1 *et seq.*). Only the New Mexico Medicaid FCA refers to an "affected person" being able to bring a *qui tam* action. *See* N.M. Stat. Ann. § 27-14-7(B). The Fraud Against Taxpayers Act states that a "person may bring a civil action," without using the "affected" modifier. N.M. Stat. Ann. § 44-9-5.

[25] Interestingly, Delaware amended the definitions section in 2009, and deleted the definition of "affected person." Relators, however, argue that the court should consider the definition of "affected person" prior to the 2009 amendments and disregard the requirements from the Del. Substantial Evidence Section from that earlier version of the Delaware False Claims and Reporting Act

of the term when one considers its ordinary meaning, as it is hard to fathom how every employee of a nationwide firm could be affected by violations of New Mexico's FCA. The court therefore declines to impose the Delaware General Assembly's definition of "affected person" on the New Mexico statute. Under the term's ordinary meaning, "affected person" does not include Doe and King. Accordingly, they are not eligible to bring a claim under the New Mexico statute. SPI's motion to dismiss the § 27-14-1 *et seq.* claims asserted in Count 22 (New Mexico) is GRANTED, and Relators' claims under the New Mexico FCA are DISMISSED WITH PREJUDICE.

3. Texas, New Hampshire, and Maryland (Counts 20, 27, and 30)

SPI moves to dismiss Relators' claims under the Texas, New Hampshire, and Maryland FCAs (Counts 20, 27, and 30, respectively), contending that the Texas, New Hampshire, and Maryland FCAs do not permit Relators to litigate FCA actions that those states have declined to take over. Dkt. 122 at 35. Relators argue that an amendment to the Texas statute makes dismissal of the Texas claims inappropriate, and that New Hampshire and Maryland have not yet declined to intervene, so relators may continue to pursue these claims. Dkt. 131 at 37. First, the court notes that both New Hampshire and Maryland *have* declined to intervene. *See* Dkt. 50 (Nov. 20, 2009) (notice of non-intervention of New Hampshire and several other states); Dkt. 138 (Feb. 17, 2011) (State of Maryland's notice of election to decline intervention). Thus, the court must determine if the statutes of those states mandate dismissal after an election not to intervene. The court will address each state in turn.

a. Texas (Count 20)

The Texas FCA has been amended since the commencement of this lawsuit, and the amendment became effective on May 4, 2007. The version that was in effect at the time this lawsuit

was filed required the court to dismiss the action if the State of Texas declined to take over the action. Tex. Human Res. Code Ann. § 36.104 (Vernon 2001). The new version of the statute states that if the State of Texas declines to take over the action, "the person bringing the action may proceed without the state's participation." Tex. Human Res. Code Ann. § 36.104 (Vernon Supp. 2010) (amended May 4, 2007). SPI argues that the claims in this case arose while the former version of the statute was in place and that the former version is therefore the version that should apply. Dkt. 139 at 23. Relators argue that (1) the State of Texas's notice of non-intervention was filed after the statute was amended; (2) the notice does not mandate dismissal of the claims; and (3) some of Solvay's conduct that allegedly violated the Texas FCA occurred after the 2007 amendment and cannot be divided from the conduct occurring before for the purposes of a motion to dismiss. Dkt. 131 at 37.

The 2007 amendments apply "only to conduct that occurs on or after the effective date . . . of [the] Act. Conduct that occurs before the effective date of [the] Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose." Tex. Human Res. Code Ann. § 36.104 (Vernon Supp. 2010) (Historical and Statutory Notes). The "conduct" discussed in section 36.104 is the State of Texas's election not to intervene. The State of Texas filed its amended notice of non-intervention on October 5, 2009. Dkt. 45. Thus, the "conduct" occurred after the statute was amended. At the point the State of Texas declined to intervene, thus triggering section 36.104(b), the section allowed a *qui tam* relator to proceed without the State of Texas' participation. Therefore, the relevant Texas statute does not prohibit Relators from maintaining an action on Texas' behalf, and SPI's motion to dismiss the Texas FCA claims (Count 20) on this basis is DENIED.

b. New Hampshire (Count 27)

The New Hampshire statute has likewise been amended since this lawsuit commenced. The version in effect when the action commenced stated that the action should be dismissed if the state declined to intervene. *See* N.H. Rev. Stat. § 167.61-c(II)(e) (2004). The amended version, which was enacted on June 29, 2009, states that "the relator who initiated the proceeding may conduct the action" if the State of New Hampshire declines to intervene. N.H. Rev. Stat. § 167.61-c(II)(e) (2009). The bill amending this section indicates that the act would "take effect upon its passage." S.B. 174, 161st Leg., 1st Sess. Gen. Ct. (N.H. 2009). Thus, the amendment is not retroactive. However, New Hampshire declined to intervene on November 20, 2009, which is *after* the new section took effect. Like the Texas section at issue, the New Hampshire section at issue is triggered once the state declines to intervene. Thus, it was only triggered *after* the amendment to the statute. Accordingly, SPI's motion to dismiss the claims on behalf of New Hampshire (Count 27) on this basis is DENIED.

c. Maryland (Count 30)[26]

The Maryland Code of Health-General section 2-604(a)(7) states: "If the State does not elect to intervene and proceed with the action . . . before unsealing the complaint, the court shall dismiss the action." Md. Code Ann. Health-Gen. § 2-604(a)(7) (West 2011). Here, the State of Maryland did not elect to intervene before the complaint was unsealed and, in fact, declined to intervene after the complaint was unsealed. *See* Dkt. 138. In its election not to intervene, the State of Maryland stated that it was notifying the court pursuant to section 2-604(a)(6)(ii) of its Code of Health-

[26] In Part II.E.6, *infra*, the court dismisses all claims under the Maryland FCA with prejudice. It addresses the motion for dismissal under section 2-605(a)(7) as an alternative means of dismissal.

General, and that it was reserving its rights under section 2-603 of its False Health Claims Act to intervene at a later date upon a showing of good cause. *Id.* Subsection 2-604(a)(6)(ii) simply indicates that the State of Maryland must notify "the court that it will not intervene and proceed with the action" if it does not elect to intervene. Md. Code Ann. Health-Gen. § 2-604(a)(6)(ii). The relevant portion of section 2-603 states that the State of Maryland may file a civil action if it "finds that a person has violated or is violating § 2-602(a)" of the Maryland False Health Claims Act. Md. Code Ann. Health-Gen. § 2-603(a).[27] SPI's motion to dismiss the claims against Maryland in accordance with the plain language of section 2-604(a)(7) is GRANTED. Relators' claims on behalf of the State of Maryland (Count 30) are DISMISSED.

4. Fraud Occurring Before a State's FCA Enactment.

SPI moves to dismiss each state claim to the extent it is based on allegedly fraudulent claims submitted prior to the state FCAs' effective dates. Dkt. 122 at 36. SPI specifically contends that sixteen (16) of the state counts involve a statute post-dating some of all of the alleged misconduct that either is silent or explicitly forbids retroactive application—Colorado (effective 5/26/10, silent on retroactivity), Connecticut (effective 10/5/09, silent on retroactivity), Delaware (6/30/00, silent on retroactivity), Georgia (effective 5/24/07, silent on retroactivity), Hawaii (effective 5/26/00, silent on retroactivity), Indiana (effective 5/11/05, silent on retroactivity), Minnesota (effective July 1, 2010, silent on retroactivity), Montana (effective 10/1/05, applies after 10/1/05), New Hampshire (effective 1/1/05, applies after 1/1/05), New Jersey (effective 3/13/08, silent on retroactivity), New Mexico (effective 5/19/04, silent as to retroactivity), New York (4/1/07, silent as to retroactivity),

[27] It is unclear why the State of Maryland reserved the right to intervene in the future under section 2-603 when section 2-604(a)(7) requires the court to dismiss the claims Relators asserted on behalf of Maryland.

Oklahoma (11/1/07, silent as to retroactivity), Rhode Island (effective 2/15/08, silent as to retroactivity), Virginia (effective 1/1/03, silent as to retroactivity), and Chicago (12/15/04, silent as to retroactivity). Dkt. 122 at 36-37 & Exh. A. Relators concede some of these points, but they argue that North Carolina and Maryland specifically allow for retroactive application of their statutes if the limitations period has not run and that the state FCAs that are silent with regard to retroactivity should be applied retroactively. Dkt. 131 at 38. Relators also generally allege that each state FCA claim is an "indivisible claim that may not be carved up." Dkt. 131 at 39. Relators cite an unpublished decision from the District of South Dakota for this proposition. *Id.* (citing *Janis v. Nelson*, No. CR. 09-5019-KES, 2009 WL 4505935, at *7 (D.S.D. Nov. 24, 2009)). In that case, the plaintiff sought to dismiss the type of *relief* sought in each count, not simply portions of the claims. *Janis*, 2009 WL 4505935, at *6. Here, SPI requests dismissal of a portion of the substantive claim. Dismissing these portions of the substantive claims, to the extent dismissal is warranted, helps streamline the issues, making preparation for trial easier on all parties. Thus, the court does not find Relators' argument that it should not dismiss portions of the claims persuasive.

The court will first discuss the parties' general arguments with regard to retroactivity, and it will then specifically address the claims under the state FCAs that are addressed in the parties' briefing.[28]

[28] SPI asserts, in general, that the "court should dismiss each state claim to the extent it is based on allegedly fraudulent claims submitted prior to state FCA's effective date." Dkt. 122 at 36. It only provides arguments relating to sixteen state FCAs. *See id.* at 36-37 & Exh. A. Relators do not address each of these sixteen states specifically in their response, but they do address two states not specified in SPI's motion—Massachusetts and North Carolina. *Compare* Dkt. 122 at 38 & Exh. A, *with* Dkt. 131 at 38. The court addresses only the state FCAs that were specifically argued by the parties. To the extent SPI means to assert the same arguments with regard to other state FCAs, its motion with regard to the unspecified states is DENIED.

a. Retroactivity, in General

Relators argue that the state FCAs in Delaware, Georgia, Hawaii, Massachusetts, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, and Virginia should be applied retroactively since the statutes are silent on retroactivity. Dkt. 131 at 38. Relators contend that the statutes that are silent on the issue of retroactivity should be applied retroactively if doing so is not contrary to express legislative history or does not result in manifest injustice. Dkt. 131 at 38. Relators rely on *Bradley v. School Board of City of Richmond*, 416 U.S. 696, 711, 94 S. Ct. 2006 (1974), for this argument. Dkt. 131 at 38-39. Solvay contends that the Supreme Court directly rejected Relators' reading of *Bradley* in *Landgraf v. USI Film Products*, 511 U.S. 244, 114 S. Ct. 1483 (1994). Dkt. 139 at 24. Additionally, Solvay argues that the Supreme Court has refused to read retroactivity into the federal FCA at least twice. *Id.* (citing *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, __ U.S. __, 130 S. Ct. 1396, 1400 n.1 (2010) (noting that the PPACA legislation made "no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates petitioners' claimed defense to a *qui tam* suit"); *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 950, 117 S. Ct. 1871 (1997) (noting that the 1986 amendment, which spoke "to the substantive rights of the parties," "is as much subject to [the Court's] presumption against retroactivity as any other").

The United States Supreme Court, in *Bradley*, "anchor[ed] its holding . . . on the principle that a court is to apply the law in effect at the time it renders its decision, unless doing so would result in manifest injustice or there is statutory direction or legislative history to the contrary." 416 U.S. 696, 711, 94 S. Ct. 2006 (1974). The court rejected "the contention that a change in the law is to given effect in a pending case only where that is the clear and stated intention of the

legislature." *Id.* at 715. The court declined to hold that "courts must always . . . apply new laws to pending cases in the absence of clear legislative direction to the contrary," but noted that since the legislative history of the statute in question could be supportive of either position (applying the new law or the old), "it would seem to provide at least implicit support for the application of the statute to pending cases." *Id.* at 716.

In *Landgraf*, the Supreme Court "clarified the circumstances in which a new statute which itself does not explicitly state whether it applies to pending cases should be applied retroactively." *Hartford Cas. Ins. Co. v. F.D.I.C.*, 21 F.3d 696, 700 (5th Cir. 1994) (citing *Landgraf*, 511 U.S. 244). The *Landgraf* Court noted that it "did not intend to displace the traditional presumption against applying statutes affecting *substantive* rights, liabilities, or duties to conduct arising before their enactment" with the *Bradley* decision. 511 U.S. at 278. It noted that although the language in *Bradley* "suggests a categorical presumption in favor of application of *all* new rules of law," it was making "clear" with the *Landgraf* decision "that *Bradley* did not alter the well-settled presumption against application of the class of new statutes that would have genuinely 'retroactive' effect." *Id.* at 277.

Thus, the *Landgraf* Court enunciated the following standard:

> When a case implicates a federal statute enacted after the events in a suit, the court's first task is to determine whether Congress has expressly prescribed the statute's proper reach. If Congress has done so, of course, there is no need to resort to judicial default rules. When, however, the statute contains no such express command, the court must determine whether the new statute would have retroactive effect, *i.e.*, whether it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed. If the statute would operate retroactively, our traditional presumption teaches that it does not govern absent clear congressional intent favoring such a result.

Id. at 280.

Relators claim that retroactive application of the state FCAs does not impair any of Solvay's rights, increase Solvay's liability, or impose new duties, and that the court should thus apply them retroactively in accordance with the *Bradley* decision. Dkt. 140-1 at 17-18. The *Landgraf* Court, however, instructed that courts must determine first whether Congress expressly made the statute retroactive and, if not, if the statute would have retroactive effect. Applying the State FCAs that were not in effect at the time the events giving rise to this lawsuit occurred would certainly have retroactive effect—Solvay would be held accountable for conduct that occurred at a time when it had no notice that such conduct would be in violation of the State FCAs at issue, since they were not even enacted yet. Thus, under *Landgraf*, the new FCAs should not be applied unless there is clear legislative guidance that it is proper to do so.

However, in both *Bradley* and *Landgraf* the United States Supreme Court was discussing whether it was appropriate to apply *federal* statutes retroactively. Here, the issue is whether *state* statutes should be given retroactive effect when the state legislatures did not provide any guidance. Thus, the court must consider how each state or locality at issue treats retroactivity issues.

b. Chicago, New Hampshire, and Montana

Since the court already dismissed the Chicago claims on other grounds, it will not address SPI's argument that the Chicago claims occurring before the statute was enacted should be dismissed. Relators concede that the Montana FCA applies only to claims submitted after October 1, 2005 and that the New Hampshire FCA applies only to claims submitted after January 1, 2005. *Id.* Thus, the alleged violations of the Montana FCA occurring before October 1, 2005 and the

alleged violations of the New Hampshire FCA occurring after January 1, 2005 are DISMISSED WITH PREJUDICE.

c. Delaware, Georgia, Hawaii, Indiana, Massachusetts, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, and Virginia

SPI argues that Relators' claims with regard to alleged violations occurring before the enactment of state FCAs for sixteen state that are either silent of expressly forbid retroactive application should be dismissed. Dkt. 122 at 37. Relators argue that ten of these states, Delaware, Georgia, Hawaii, Indiana, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, and Virginia, plus one state FCA not specified by SPI, Massachusetts, are all silent on retroactivity and should be applied retroactively as long as no manifest injustice results.

i) Delaware (Count 10). "In Delaware, there is a 'presumption against retroactivity.' Laws apply retroactively only where the General Assembly has made its intent plain and unambiguous." *A.W. Fin. Servs., S.A. v. Empire Res., Inc.*, 981 A.2d 1114, 1120 (Del. 2009) (quoting *State ex rel. Brady v. Pettinaro Enter.*, 870 A.2d 513, 529 (Del. Ch. 2005)). The Delaware False Claims and Reporting Act was enacted on June 30, 2000. Del. Code Ann. tit. 6, § 1201 (West, Westlaw current through 78 Laws 2011, chs. 1-104) (credits); 2000 Del. Laws Ch. 370 (H.B. 543) (West). Its prohibitions mirror the federal FCA and other state FCAs. *See* Del. Code. Ann. tit. 6, § 1201 *et seq.* It is silent regarding whether it is retroactive. Thus, the presumption against retroactivity applies. SPI's motion as it relates to the enactment of the Delaware statute is GRANTED. Relators' claims under the Delaware statute, to the extent they are based on alleged fraudulent claims for payment or approval or alleged false records or statements made to get a false

or fraudulent claim paid or approved by the Delaware government prior to the enactment date of the Delaware False Claims and Reporting Act, July 30, 2000, are DISMISSED WITH PREJUDICE.

ii) Georgia (Count 16). In Georgia, "legislation which involves mere procedural or evidentiary changes may operate retrospectively; however, legislation which affects substantive rights may only operate prospectively." *Fowler Props., Inc. v. Dowland*, 646 S.E.2d 197, 200 (Ga. 2007). In fact, the Georgia Constitution states, "No bill of attainder, ex post facto law, retroactive law, or laws impairing the obligation of contract or making irrevocable grant of special privileges or immunities shall be passed." Ga. Const. art. 1, § 1, ¶ X. The Georgia False Medicaid Claims Act was effective on May 24, 2007. Ga. Code Ann. § 49-4-168.1 (West, Westlaw through 2011 Reg. Sess.). It parallels the federal statute, making any person who "[k]nowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval," who "[k]nowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;" or "[c]onspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid," liable to the State of Georgia.[29] *Id.* Because the Georgia statute was not enacted until May 24, 2007, and cannot apply retroactively, SPI's motion relating to the enactment of the Georgia False Medicaid Claims Act is GRANTED, and Relators' claims based on the Georgia statute, to the extent they request relief for alleged false or fraudulent claims, records, or statements made prior to May 24, 2007, are DISMISSED WITH PREJUDICE.

[29] The Georgia statute was amended in 2009, but the relevant subsections were not impacted. *See* 2009 Ga. Laws Act 8 (S.B. No. 46).

iii) Hawaii (Count 13). The Hawaii Supreme Court, in *Taniguchi v. Association of Apartment Owners of King Manor, Inc.*, noted that "it is well settled that 'all statutes are to be construed as having only a prospective operation unless the purpose and intention of the legislature to give them a retrospective effect is expressly declared or is necessarily implied from the language used.'" 155 P.3d 1138, 1149 (Haw. 2007) (quoting *Robinson v. Bailey*, 28 Haw. 462, 464 (1925)). The Hawaii version of the FCA was enacted on May 26, 2000, and the Hawaii Legislature noted that it would "take effect upon its approval." 2000 Haw. Laws Act 126 (S.B. 2115). Under the act, "any person who . . . [k]nowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval; [k]nowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; [or] [c]onspires to defraud the State by getting a false or fraudulent claim allowed or paid;" shall be liable to the State of Hawaii. Haw. Rev. Stat. § 661-21(a)(1)-(3) (West, Westlaw current through Act 235 of the 2011 Reg. Sess.). Since this act was not enacted until May 26, 2000, and it not retroactive, SPI's motion to dismiss as it relates to the enactment of the Hawaii statute is GRANTED, and Relators' claims under the Hawaii statute, to the extent they are based on any alleged false claim presented, false record or statement made, or conspiracy entered into before May 26, 2000, are DISMISSED WITH PREJUDICE.

iv) Indiana (Count 17). In Indiana, "absent an express indication otherwise, [courts applying Indiana law] presume that the legislature intended that the statute be applied prospectively only." *Robinson v. Valladares*, 738 N.E.2d 278, 281 (Ind. Ct. App. 2000). The Indiana legislature enacted the Indiana False Claims and Whistleblower Protection statute on May 11, 2005, and the legislature noted that it was effective on July 1, 2005. 2005 Ind. Legis. Serv. P.L

222-2005 (H.E.A. 1501) (West). Section 5-11-5.5-2 of the act states that a "person who knowingly or intentionally: (1) presents a false claim to the state for payment or approval; (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state; [or] . . . (7) conspires with another person to perform the act described in subdivisions (1) through (6); . . . is . . . liable to the state for a civil penalty." Ind. Code Ann. § 5-11-5.5-2(a)(1), (2), (7) (West 2008). Thus, since the Indiana legislature specifically indicated that the statute was effective on July 1, 2005, SPI's motion to dismiss as it pertains to Relators' claims arising from alleged false claims, false records or statements, or conspiracies to present false claims or make or use false records under the Indiana statute, that occurred before July 1, 2005, is GRANTED and these claims are DISMISSED WITH PREJUDICE.

v) Massachusetts (Count 8). According to the Massachusetts Supreme Court, a "fundamental and well-established principle of statutory interpretation 'is that a statute must be interpreted according to the intent of the Legislature ascertained from all its words construed by the ordinary and approved usage of language, considered in connection with the cause of its enactment, the mischief of imperfection to be remedied and the main object to be accomplished, to the end that the purpose of its framers may be effectuated.'" *Fleet Nat'l Bank v. Comm'r of Revenue*, 862 N.E.2d 22, 28 (Mass. 2007) (quoting *Hanlon v. Rollins*, 190 N.E. 606 (1934)). If the "language of a statute is unambiguous, [courts] simply give effect to the Legislature's intent." *Id.* However, if the intent is not clear, as "a general matter, 'all statutes are prospective in their operation, unless an intention that they shall be retrospective appears by necessary implication from their words, context or objects when considered in the light of the subject matter, the pre-existing state of the law and the effect upon existent rights, remedies and obligations." *Id.*

The Massachusetts FCA took effect on July 1, 2000. *See* 2000 Mass. Legis. Serv. Ch. 159 (H.B. 5300) (West). It was part of the appropriations act for the fiscal year 2001, and the legislature specifically provided that various sections of the act should either take effect on future dates, or with one section, take effect retroactively. *See id.* However, the effective date for the section outlining the FCA was not specified. *See id.* The legislature instructed, however, that "except as otherwise provided, this act shall take effect on July 1, 2000." *Id.* The Massachusetts legislature therefore meant for the FCA to take effect on July 1, 2000.

The Massachusetts FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; "knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim"; or "conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim . . . ." Mass. Gen. Laws Ann. 12 § 5B. Because the Massachusetts FCA did not take effect until July 1, 2000, any violations of the statute that occurred prior to July 1, 2000 are not covered by the statute. Accordingly, SPI's motion for partial dismissal of the Massachusetts FCA claims is GRANTED. The Massachusetts FCA claims relating to alleged violations occurring before July 1, 2000 are DISMISSED WITH PREJUDICE.

vi) New Jersey (Count 21). In New Jersey, there is a presumption against retroactivity, but there are also "three judicially crafted categories favoring retroactivity": "(1) the Legislature has expressed, either expressly or implicitly, its intent that the statute apply retroactively; (2) the statute is 'curative'; or (3) the expectations of the parties warrant the retroactive application of the statute." *Olkusz v. Brown*, 951 A.2d 1069, 1073 (N.J. Super. Ct. App. Div. 2008). The "curative" exception applies if a statute "is designed merely to carry out or explain the intent of the

original statute." *Kendall v. Snedeker*, 530 A.2d 334, 336 (N.J. Super. Ct. App. Div. 1987). The "curative" exception does not apply if the amendment "simply improves upon an existing statutory scheme." *Olkusz*, 951 A.2d at 1074.

The New Jersey FCA was approved on January 13, 2008, and the legislature specifically stated that it was to "take effect on the 60th day after enactment"—March 13, 2008. N.J. Stat. Ann. § 2A:32C-1 (West 2010). None of the exceptions to the presumption against retroactivity applies. Under the New Jersey FCA, a person is liable to the State of New Jersey if the person "a. Knowingly presents or causes to be presented to an employee or officer or agent of the State [of New Jersey], or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval; b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State [of New Jersey]; [or] c. Conspires to defraud the State [of New Jersey] by getting a false or fraudulent claim allowed or paid by the State." *Id.* § 2A:32C-3. Since this statute did not take effect until March 13, 2008 and does not apply retroactively, SPI's motion to dismiss Relators' claims as they relate to alleged false or fraudulent claims made to the State of New Jersey, false records or statements to get a false or fraudulent claim paid or approved by the State of New Jersey, or conspiracies to defraud the State of New Jersey, under the New Jersey statute and before March 13, 2008, is GRANTED, and these claims are DISMISSED WITH PREJUDICE.

vii) New Mexico (Count 22). "New Mexico law presumes that statutes and rules apply prospectively absent a clear intention to the contrary." *Howell v Heim*, 882 P.2d 541, 547 (N.M. 1994). "A statute or regulation is considered retroactive if it impairs vested rights acquired under prior law or requires new obligations, imposes new duties, or affixes new disabilities

to past transactions." *Id.* Relators added claims under the New Mexico Fraud Against Taxpayers Act (N.M. Stat. Ann. 1978, §§ 44-9-1 *et seq.*) in the third amended complaint. This statute was approved by the New Mexico Legislature on March 15, 2007, and the New Mexico Legislature specifically stated that its effective date was July 1, 2007. 2007 N.M. Laws Ch. 40 (H.B. 770) (Westlaw). The act prohibits persons from "knowingly present[ing], or caus[ing] to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval; . . . knowingly mak[ing] or us[ing] or caus[ing] to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment of a false or fraudulent claim; . . . [or] conspir[ing] to defraud the state [of New Mexico] by obtaining approval or payment on a false or fraudulent claim." N.M. Stat. Ann. 1978, § 44-9-3. The New Mexico Legislature specified the date on which the statute was to be effective. Moreover, the statute imposes new penalties upon persons for certain actions, so it would have retroactive effect. Thus, under New Mexico law, it should only be applied prospectively—as of July 1. 2007. SPI's motion to partially dismiss Relators' claims under the New Mexico Fraud Against Taxpayers Act is GRANTED. All claims under this act relating to claims, records or statement, or conspiracies occurring before July 1, 2007 are DISMISSED WITH PREJUDICE.

viii) New York (Count 23). Under New York law, an "amendment to a statute will only be given retroactive effect in the exceptional case where the Legislature declares it so," and "[w]here a new right of action is created, . . . the presumption is that it is prospective, not retroactive, unless there is clearly a contrary legislative intent." *Logan v. Salvation Army*, 809 N.Y.S.2d 846, 849 (N.Y. Sup. Ct. 2005). The New York FCA was approved on April 9, 2007, and

the New York Legislature noted that it was to "take effect immediately and [was] deemed to have been in full force and effect on and after April 1, 2007." 2007 Sess. Laws of N.Y. Ch. 59 (S. 2108-C) (McKinney). There is thus no reason to apply the statute to claims arising before April 1, 2007.

Under the relevant portions of the New York FCA, "any person who: (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval; (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] conspires to commit a violation of paragraph (a), (b), (d), (e), (f) or (g) of this subdivision . . . shall be liable [under the statute]." N.Y. State Fin. Law § 189 (McKinney 2007). Since this provision was not in force until April 1, 2007 and is not retroactive, SPI's motion as it relates to the enactment of the New York FCA is GRANTED, and Relators' claims under the New York statute pertaining to alleged false or fraudulent claims for payment to the State of New York, false records or statements material to a false New York claim, or conspiracies to commit a violation of the New York FCA that occurred before April 1, 2007 are DISMISSED WITH PREJUDICE.

ix) Oklahoma (Count 24). In *Cole v. Silverado Foods, Inc.*, the Oklahoma Supreme Court instructed:

> Absent a plain legislative intent to the contrary, statutes are generally presumed to operate prospectively only. Legislation that is general in its terms and impacts only matters of procedure is presumed to be applicable to all actions, even those that are pending. Statutes that relate solely to remedies and hence affect only modes of procedure - *i.e. enactments that do not create, enlarge, diminish, or destroy accrued or contractual rights* - are generally held to operate retroactively and apply to pending proceedings (unless their operation would affect substantive rights).

2003 OK 81, ¶ 8, 78 P.3d 542, 546. The Oklahoma Medicaid FCA was approved May 14, 2007 and became effective November 1, 2007. 2007 Okla. Sess. Law Serv. Ch. 137 (S.B. 889) (West). There is no plain legislative intent that the statute should apply retroactively, and it does not affect only

a mode of procedure as it creates a substantive cause of action. Thus, there is no reason to apply the statute retroactively.

The relevant portion of the Oklahoma Medicaid FCA states that any "person who: 1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval; 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; [or] 3. Conspires to defraud the state by getting a false or fraudulent claim allowed or paid . . . is liable to the State of Oklahoma for a civil penalty." Okla. St. Ann. tit. 63, § 5053.1 (West, Westlaw current through 1st Reg. Sess. of the 53rd Legis.). This statute applies only to alleged false or fraudulent claims for payment or approval made to the State of Oklahoma, false records or statements to get a false or fraudulent claim paid or approved by the State of Oklahoma, or conspiracies to defraud the State of Oklahoma that occurred on or after November 1, 2007. SPI's motion with regard to the Oklahoma statute is GRANTED. Relators' claims under the Oklahoma statute as they pertain to alleged claims, records, or conspiracies occurring before November 1, 2007 are DISMISSED WITH PREJUDICE.

x) Rhode Island (Count 25). The Rhode Island Supreme Court, in *Direct Action for Rights & Equality v. Gannon*, noted that it "presumes that statutes and their amendments operate prospectively unless there is clear, strong language or a necessary implication that the [Rhode Island] General Assembly intended to give the statute retroactive effect." 819 A.2d 651, 658 (R.I. 2003). However, if "a statute lacks such clear, strong language or there is no necessary implication concerning its retroactive application, the distinction between a substantive statute and a remedial, or procedural, statute becomes very important." *Id.* While substantive statutes, "which

create, define, or regulate substantive legal rights, must be applied prospectively, . . . remedial and procedural statutes, which do not impair or increase substantive rights but rather prescribe methods for enforcing such rights, may be construed to operate retroactively." *Id.* (quotations and citation omitted).

The Rhode Island FCA is similar substantively to the other state FCAs and the federal FCA, and it certainly, therefore, cannot be deemed a remedial or procedural statute, as it creates civil liability. The statute, known as the State False Claims Act, became effective on July 1, 2007. R.I. Gen. Laws 1956, § 9-1.1-3 (West, Westlaw current through ch. 407 of the Jan. 2011 sess.). The Rhode Island State FCA, in relevant part, makes any "person who: (1) knowingly presents, or causes to be presented, to an officer or employee of the state [of Rhode Island] or a member of the guard a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; [or] conspires to defraud the state by getting a false or fraudulent claim allowed or paid . . . liable to the state [of Rhode Island]." *Id.* Since this statute did not become effective until July 1, 2007, and is not retroactive, SPI's motion as it relates to the Rhode Island statute's enactment is GRANTED, and Relators' claims under the Rhode Island State FCA that arise from alleged false or fraudulent claims to the State of Rhode Island, false records or statements to get a false or fraudulent claim paid or approved by the State of Rhode Island, or conspiracies to defraud the State of Rhode Island, to the extent these claims arose before July 1, 2007, are DISMISSED WITH PREJUDICE.

xi) Virginia (Count 15). In *Berner v. Mills*, the Virginia Supreme Court based its analysis on "the fundamental principles of statutory construction that retroactive laws are

not favored, and that a statute is always construed to operate prospectively unless a contrary legislative intent is manifest." 579 S.E.2d 159, 161 (Va. 2003). The Virginia FCA, known as the Virginia Fraud Against Taxpayers Act, was enacted on January 1, 2003. *See* Va. Code Ann. § 8.01-216.3(3), *et seq.* (West, Westlaw through Acts of 2011, c. 676). The Historical and Statutory Notes accompanying the statute state that "the provisions of this act shall become effective January 1, 2003." *Id.* There is no evidence of legislative intent that the statute should be applied retroactively. Thus, SPI's motion to dismiss as it relates to the enactment of the Virginia Fraud Against Taxpayers Act is GRANTED. To the extent that any of the claims under the Virginia Fraud Against Taxpayers Act occurred before January 1, 2003, in that any alleged false or fraudulent claims for payment or approval were knowingly presented, any alleged false records or statements material to a false or fraudulent claim were knowingly made, or any related conspiracies entered into prior to January 1, 2003, Relators' claims relating to those claims, records, or statements that are asserted under the Virginia Fraud Against Taxpayers Act are DISMISSED WITH PREJUDICE.

d. Colorado, Connecticut, Minnesota

SPI argues that any alleged violations of the Colorado, Connecticut, and Minnesota FCAs occurring before these statutes were enacted should be dismissed. *See* Dkt. 122 at 37 (specifying these state FCAs as three of the sixteen that should be partially dismissed under its enactment date argument). Relators do not assert specific arguments relating to the FCAs of these three states. However, Relators do assert a general argument that the court should apply the state FCAs retroactively because doing so does not deprive Solvay of rights, impose new obligations, or result in "manifest injustice."

i) Colorado (Count 28). In *People v. Summers*, the Colorado Supreme Court stated that it must turn to "other aids of statutory construction" when "legislative history fails to reveal the legislative intent behind the bill." 208 P.3d 251, 256 (Colo. 2009). "One such aid in Colorado is the presumption that statutes apply prospectively," which the Colorado General Assembly can only override "by clearly expressing a contrary intent." *Id.* (citing Colo. Rev. Stat. § 2-4-202 (2008); *Riley v. People*, 828 P.2d 254, 256 (Colo. 1992)). "The presumption of prospective application is only strengthened by the insertion of an effective date clause that explicitly mandates prospective application." *Id.* at 257.

The current version of the Colorado Medicaid FCA was "reenacted" on May 26, 2010. Colo. Rev. Stat. Ann. § 25.5-4-305 (West, Westlaw through Laws of 2011, Ch. 264, § 66). The Colorado Legislature indicated that the effective date of the relevant parts of the statute was "upon passage." *Id.* (notes). The legislative history of the statute indicates that section 25.5-4-305 is a recodification of the former 26-4-1103(1) and (2), with slight changes to the wording. This recodification occurred on July 1, 2006. Both the former and the recodified versions made it unlawful to "[i]ntentionally or with reckless disregard make or cause to be made any false representation or a material fact in connection with a claim;" or "[i]ntentionally or with reckless disregard present or cause to be presented to the state department a false claim for payment or approval." 2006 Colo. Legis. Serv. ch. 355 (S.B. 06-219). The section (the former Colo. Rev. Stat. Ann. § 26-4-1103) appears to be from the 2001 statutory compilation. *See* Colo. Rev. Stat. Ann. § 25.5-4-305 (West, Westlaw through Laws of 2011, Ch. 264, § 66) (notes–derivation). Colorado, therefore, has had some version of an FCA since at least 2001. SPI's motion to dismiss the Colorado claims arising prior to the 2010 reenactment of the Colorado Medicaid FCA (Count 28) is DENIED.

ii) Connecticut (Count 29).[30] According to the Connecticut Supreme Court, "The principles that govern retroactive application of legislative enactments are well-established. Except as to amending statutes that are procedural in their impact, there is a general presumption that legislation is intended to operate prospectively." *Enfield Fed. Sav. & Loan Ass'n v. Bissell*, 440 A.2d 220, 221 (Conn. 1981). SPI claims that Connecticut's FCA was enacted on October 5, 2009, and that Relators' claims based on conduct occurring before that time should be dismissed. Under section 17b-301b of the Connecticut General Statutes Annotated, "No person shall . . . [k]nowingly present . . . a false or fraudulent claim for payment . . ., [k]nowingly make, use or cause to be made or used, a false record or statement to secure payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the [Connecticut] Department of Social Services[, or] [c]onspire to defraud the state [of Connecticut] by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the [Connecticut] Department of Social Services."[31] Conn. Gen. Stat. Ann. § 17b-301b(a)(1)-(2) (West, Westlaw through Gen. St., Rev. to 1-1-2011). This section became effective on October 5, 2009. *Id.* This is certainly not a procedural statute, so the presumption is that it is prospective. Thus, any alleged false or fraudulent claims for payment, records, or statements to secure payment by the State of Connecticut, or conspiracy under a medical assistance program administered by the Connecticut Department of Social Services that was made prior to October 5, 2009, is not covered by the statute.

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[30] In Part II.E.6, *infra*, the court dismisses all claims under the Connecticut FCA with prejudice. It addresses the motion for partial dismissal with regard to the enactment date as an alternative means of dismissal.

[31] The statute was amended in 2011; the amendments appear to mirror the PPACA amendments to the federal statute. 2011 Conn. Legis. Serv. P.A. 11-44 (S.B. 1240) (West). The Connecticut General Assembly indicated that the amendments were "effective from passage." *Id.*

Accordingly, SPI's motion is GRANTED, and Relators' claims, to the extent they are based on alleged violations of the Connecticut FCA prior to October 5, 2009, are DISMISSED WITH PREJUDICE.

iii) Minnesota (Count 31).[32] "Minnesota laws are presumed to have no retroactive effect unless clearly and manifestly intended by the legislature." *Mason v. Farmers Ins. Cos.*, 281 N.W.2d 344, 348 (Minn. 1979) (citing Minn. Stat. Ann. § 645.21 (West 1947) ("No law shall be construed to be retroactive unless clearly and manifestly so intended by the legislature.")). The Minnesota False Claims Against the State statute was enacted in 2009 and became effective July 1, 2010. Minn. Stat. Ann. § 15C.01 (West, Westlaw current through 2011 Reg. Sess.). It imposes liability on any person who "(1) knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval; (2) knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision; [or] (3) knowingly conspires to either present a false or fraudulent claim . . . or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim." *Id.* § 15C.02(a)(1)-(3). Because the Minnesota legislature stated the statute was to be effective on July1, 2010, there is no clear and manifest intention by the legislature that the statute be applied retroactively. Accordingly, SPI's motion to dismiss as it pertains to Relators' claims arising from allegedly false or fraudulent claims or false records or statements made before July 1, 2010, or conspiracies entered into before

[32] In Part II.E.6, *infra*, the court dismisses all claims under the Minnesota FCA with prejudice. It addresses the motion for partial dismissal with regard to the enactment date as an alternative means of dismissal.

July 1, 2010, under the Minnesota statute, is GRANTED, and these claims are DISMISSED WITH PREJUDICE.

e. North Carolina (Count 32) and Maryland (Count 30)

SPI does not specifically address the North Carolina and Maryland FCAs in the portion of its motion requesting partial dismissal of state FCA claims to the extent they request relief before the statutes were enacted. Relators, however, argue that North Carolina and Maryland specifically allow for retroactive application of their statutes and that claims under these statutes should not be dismissed based on enactment date.

The Maryland statute was enacted in 2010, and the Maryland Legislature made it effective October 1, 2010. Md. Code Health-Gen. §§ 2-601 *et seq.* The Maryland Legislature, however, specified that a "civil action may be filed . . . for activity that occurred prior to October 1, 2010, if the limitations period . . . . has not lapsed." Md. Code Health-Gen. § 2-609(b). Thus, to the extent SPI moves to partially dismiss claims under the Maryland FCA occurring before its enactment, the motion is DENIED.

The North Carolina FCA was enacted in 2009. *See* N.C. Gen. Stat. Ann. § 1-605 (West, Westlaw current through Chap. 18) (Historical and Statutory Notes). The North Carolina Legislature specified that the relevant section of the act became effective January 1, 2010 but that a "civil action may be filed after January 1, 2010, under Section 1 of this act based on acts committed prior to that date if the activity would also be covered under Part 7 of Article 2 of Chapter 108A of the General Statutes and if the limitation period . . . has not lapsed." *Id.* Part 7 of Article 2 of Chapter 108 A of the General Statutes is the Medical Assistance Provider False Claims Act. N.C. Gen. Stat. Ann. § 108A-70.10. This section applies specifically to presentation of false claims

and false records or statement made, used, or caused to be made or used by providers of medical assistance under the Medical Assistance Program of North Carolina. *Id.* § 108A-70.12. Some of the allegations in the 4AC would be covered by this statute, so the North Carolina FCA, as asserted in this lawsuit, is at least partially retroactive. Accordingly, SPI's motion to partially dismiss the North Carolina FCA based on its enactment date, to the extent SPI has so moved, is DENIED.

5. State Statutes of Limitation

Relators filed their original complaint on June 10, 2003, their first amended on July 15, 2008, their second amended complaint on November 24, 2009, and their third amended complaint on September 15, 2010. Dkts. 1, 38, 54, 111. SPI moves for dismissal of several of the state FCA claims, which were raised at different points during this litigation, to the extent that the claims relate to conduct that predates the limitations periods for those state FCAs. Dkt. 122 at 37-38. The Texas FCA claim was asserted in the original complaint on June 10, 2003. SPI argues that the Texas FCA has a four-year limitations period and that therefore all claims relating to conduct occurring before June 10, 1999, should be dismissed. Dkt. 122 at 38. Relators added claims in the first amended complaint under the FCAs of ten states that SPI claims should be partially time-barred—Georgia, Indiana, Michigan, Montana, New Hampshire, New Jersey, New York, Oklahoma, Rhode Island, and New Mexico. *Id.* at 37. SPI argues that the FCAs for Georgia, Indiana, Michigan, Montana, New Hampshire, New Jersey, New York, Oklahoma, and Rhode Island have six-year limitations periods, so the claims relating to conduct occurring before July 15, 2002 under each of these states' FCAs should be dismissed, and that the limitations period for the New Mexico Medicaid FCA is 4 years, so claims under the New Mexico Medicaid FCA for conduct predating July 15, 2004 should be dismissed. *Id.* & Exh. B. SPI also argues that the FCA claim under the Wisconsin FCA, which

was raised in the second amended complaint on November 10, 2009, should be partially dismissed because the Wisconsin FCA has a ten-year limitations period. Dkt. 122 at 38. Thus, SPI moves for dismissal of the Wisconsin FCA claims insofar as they relate to conduct occurring prior to November 10, 1999. *Id.* SPI additionally asserts that the FCA claims for six states that were raised for the first time in the third amended complaint on September 15, 2010, Colorado, Connecticut, Maryland, Minnesota, North Carolina, and Chicago, should also be partially dismissed as time-barred. *Id.* at 37-38 & Exh. B. SPI alleges that each of these state FCAs have a six-year limitations period and that the claims for conduct predating September 15, 2004 under these state or local FCAs should be dismissed.

Relators assert that the statutes of limitations for the following states contain the same statute of limitations language as the federal statute, and they argue that the tolling provision in the federal FCA, rather than a flat six-year statute of limitation, should also apply to these state claims: Georgia, Indiana, Michigan, Montana, New Hampshire, New Jersey, New York, Oklahoma, and Rhode Island. Dkt. 131 at 39. Under section 3731(b) of the federal FCA,

> A civil action under section 3730 may not be brought--
> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
> whichever occurs last.

31 U.S.C. § 3731. Relators, focusing on the ten-year period in subpart 3731(b)(2), request that the court allow them to proceed with regard to alleged conduct occurring after June 1998 for the states that they allege have FCAs parallel to the federal statute. Dkt. 131 at 39.

Relators also appear to argue that the court should apply the ten-year period to the Texas FCA claims because the Texas statute does not have an express limitations period. *Id.* SPI alleged that the four-year catchall limitations period in section 16.051 of the Texas Civil Practice and Remedies Code should apply, but Relators claim that this argument "contradicts Texas' desire to be considered qualified to receive additional Medicaid funding under the Deficit Reduction Act ("DRA") by having provisions that are at least as effective as those in the federal FCA." Dkt. 131 at 39-40 & n.30 (citing 42 U.S.C. § 1396h).

a. New Mexico, Chicago, Georgia, Indiana, Montana, New Hampshire, New York, Oklahoma, Rhode Island, Connecticut, and Minnesota

While SPI moves to partially dismiss the state FCA claims for eighteen states or localities because the claims are allegedly partially time-barred (Dkt. 122 at 37-38), the court finds it unnecessary to address SPI's motion to dismiss claims under the New Mexico and Chicago statutes because it has completely dismissed the claims under those statutes on other grounds. The court likewise finds it unnecessary to address SPI's motion to dismiss the claims under the Georgia, Indiana, Montana, New Hampshire, New Jersey, New York, Oklahoma, and Rhode Island FCAs as they relate to conduct occurring before July 16, 2004, as barred by the states' statutes of limitations, as the court has already dismissed all claims under these statutes that relate to conduct occurring before May 24, 2007, July 1, 2005, October 1, 2005, July 1, 2005, March 13, 2008, April 1, 2007, November 1, 2007, and July 1, 2007, respectively, because the statutes are not retroactive. Additionally, the court will not address SPI's motion to dismiss the claims under the Connecticut and Minnesota FCAs as they relate to conduct occurring before September 16, 2004, as barred by the states' statutes of limitations, as the court has already dismissed all claims under the Connecticut

statute that occurred before October 5, 2009, and all claims under the Minnesota statute that occurred before July 1, 2010, with prejudice because the statutes are not retroactive.

The court will thus address SPI's motion to partially dismiss for limitations with regard to the remaining states—Michigan, Wisconsin, Colorado, Connecticut, Maryland, and North Carolina. The court will first consider Relators' argument that the FCA's ten-year tolling provision should apply to the claims of parallel state provisions, and then it will address the limitations issues for each individual state.

b. Ten-Year Tolling

Relators claim that the issue of whether to allow *qui tam* relators under state FCAs to take advantage of the ten-year period in the federal FCA is unsettled in the Fifth Circuit. Dit. 131 at 39. Relators cite a Ninth Circuit case, *United States ex rel. Northrop Corp.*, an Eastern District of Texas case, *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, and an unpublished Middle District of Georgia case, *United States ex rel. Lewis v. Walker*, in support of their argument that this court should apply the ten-year period and allow the claims for conduct occurring within ten years of filing to go forward.

In *Hyatt*, the Ninth Circuit considered whether the ten-year period in subsection 3731(b)(2) should apply to *qui tam* relators or only to the U.S. Government. 91 F.3d 1211, 1213 (9th Cir. 1996). The Ninth Circuit reasoned that subsection 3731(b) plainly states that it applies to civil actions filed under section 3730 and that it therefore must have been intended to apply to civil actions filed under section 3730(a), which are claims brought by the government, and 3730(b), which are claims brought by *qui tam* relators. *See id.* at 1214. The Ninth Circuit examined the legislative history of the act and determined that it was "at best ambiguous" and that the plain

meaning of the statutory language controlled. *Id.* at 1215. Accordingly, the Ninth Circuit held that "Congress did not intend to restrict the tolling provisions of the Act to apply to suits brought by the Attorney General alone, but intended the tolling provision to apply to *qui tam* plaintiffs as well." *Id.* at 1216.

Importantly, the Ninth Circuit additionally held that, even though in the statute the ten years begins to run when an official of the U.S. government should have discovered the alleged misconduct, "the rationale behind tolling requires that the statute of limitations start to run when the plaintiff acquires knowledge of the wrongful activity, [as] [s]tatutes of limitation are used to determine 'whether the plaintiff has inexcusably slept on his rights.'" *Id.* (citing *Holmberg v. Armbrecht*, 327 U.S. 392, 396, 66 S. Ct. 582 (1946)). Thus, under *Hyatt*, "the three-year extension of the statute of limitations begins to run once the *qui tam* plaintiff knows or reasonably should have known the facts material to his right of action." *Id.* at 1217-18. The Ninth Circuit pointed out that "allowing a *qui tam* plaintiff to wait ten years might interfere with law enforcement," as if "relators wait over five years to report the fraud, the government will lose the right to seek a criminal penalty." *Id.* at 1218.

In *Foster*, the federal district court for the Eastern District of Texas also addressed whether the ten-year period in section 3731(b)(2) applies to relators and the government or just the government. 587 F. Supp. 2d 805 at 814. The court pointed out that, at the time, the only Fifth Circuit case to address the issue was an unpublished decision in which the Fifth Circuit determined, based on the legislative history of the statute, that the six-year period applied to the relator's claims. *Id.* (citing *United States ex rel. Erskine v. Baker*, No. 99-50034, 2000 WL 554644 (5th Cir. Apr. 13, 2000)). The *Foster* court then noted that other courts are divided on the issue, with some courts

holding, as the Fifth Circuit did, that an FCA *qui tam* relator is bound by the six-year limitations period, some court holding, like the *Hyatt* court, that the ten-year period applies to *qui tam* relators, but it applies from the time the relator, rather than the government, learned of the wrongdoing, and some courts holding that the ten-year limitations period applies to *qui tam* relators and tolls the limitations period until the government actually learns of the violation. See *id.* (citing *United States ex rel. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496, 509-10 (8th Cir. 2008) (collecting cases). The *Foster* court ultimately joined the courts that concluded that only the six-year statute of limitations period contained within subsection 3731(b)(1) applies to *qui tam* relators.

In *Lewis*, the federal district court in the Middle District of Georgia thoughtfully considered the same authorities discussed by the *Foster* court. No. 3:06-CV-16(CDL), 2007 WL 2713018, at *6 (M.D. Ga. Sept. 14, 2007). The court found the reasoning of the courts that have held that section (b)(2) applies to *qui tam* relators' suits persuasive, but it did not find it necessary to determine whether the tolling applied until the time of the relator's discovery or the government's discovery. *Id.*

SPI notes that the only Fifth Circuit and Texas district courts to address this issue have held that relators are bound by the six-year period in subsection (b)(1), citing *Erskine*, *United States ex rel. Gonzalez v. Fresenius Medical Care North America*, No. EP-07-CV-247-PRM, 2010 WL 1645969, at *6 (W.D. Tex. Jan. 21, 2010), and *Foster*. The court has already discussed *Foster*. In *Erskine*, the Fifth Circuit determined that the subsection (b)(2) tolling provision was "passed exclusively for the government's benefit" and that the relators, therefore, could not benefit from it. 2000 WL 554644, at *1. And in *Gonzalez*, the federal district court for the Western District of Texas, after analyzing cases reaching the three different interpretations of subsection (b)(2)

discussed in *Foster* and *Lewis*, held that in federal FCA cases where the United States does not intervene, the (b)(2) tolling provision does not apply to relators. *Id.* at *5. The court noted that it adopted this view because : "(1) it is emerging as the majority view among federal courts; (2) the Fifth Circuit indicated its agreement with the restrictive view in an unpublished opinion; and (3) the statutory language, legislative history, and practical considerations . . . support this interpretation." *Id.*

SPI also points out that other circuits have adopted this view, including the Fourth Circuit in *United States ex rel. Sanders v. North America Bus Industries, Inc.*, the Tenth Circuit in *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, and the Eleventh Circuit in *Foster v. Savannah Commication*. In *Sanders*, the Eleventh Circuit held that subsection 3731(b)(2) "extends the FCA's statute of limitations beyond six years only in cases in which the United States is a party." 546 F.3d 288, 293 (4th Cir. 2008). The Fourth Circuit based this opinion on the language of the statute, which discusses when the *government* discovered facts material to the right of action. *See id.* at 294. The Fourth Circuit stated that "applying the statute's language to a relator's action makes no sense whatsoever" because the government's knowledge "does not notify the relator of anything." *Id.* The Fourth Circuit also pointed out, similarly to the *Hyatt* court when it concluded that the tolling must apply only until *relator*'s discovery, not the government's, that "allowing relators to sit on their claims would undermine the purpose of the *qui tam* provisions of the FCA: to combat fraud quickly and efficiently by encouraging relators to bring actions that the government cannot or will not—'to stimulate actions by private parties should the prosecuting officers be tardy in bringing the suits.'" *Id.* at 295 (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 547, 63 S. Ct. 379 (1943)).

The Tenth Circuit, in *Sikkenga*, acknowledged that the text of subsection (b)(2) is ambiguous and discussed the legislative history of the statute. 472 F.3d 702, 722-25 (10th Cir. 2006). It noted that the Senate report states that "'the statute of limitations does not begin to run until the material facts are known by an official within the Department of Justice with the authority to act in the circumstances.'" *Id.* at 723 (quoting S. Rep. No. 99-345, at 30 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5295. The Tenth Circuit also considered Senator Grassley's statement explaining the amendments and testimony before the House Judiciary Committee. *See id.* & n.31 (quoting 132 Cong. Rec. S11,238 (1986) (Sen. Grassley's comments), and *False Claims Act Amendments: Hearings Before the H. Subcomm. on Admin. Law and Governmental Relations of the H. Comm. on the Judiciary*, 99th Cong. 118, 159 (1986) (Statement of Mr. Richard K. Willard, Assistant Attorney General, Dep't of Justice)). While the text of the legislative history, taken alone, supports the conclusion that subsection (b)(2) refers only to the government, the Tenth Circuit found the facts that the text and history of the FCA use the terms "government" and the "United States" to refer to both relators and the government and that Congress chose to use a general term rather than specifying the "Attorney General" as it did in other sections of the FCA "troubling." *Id.* at 724-25. However, testimony before the Senate Judiciary Committee by the Assistant Attorney General relating to the statute of limitations refers to the general statute of limitations for the federal government, which includes a tolling provision, and indicates that the proposed tolling provision for the FCA would give the Department of Justice "'a little more flexibility in bringing some cases that otherwise would be barred.'" *Id.* at 724 n.31 (quoting *False Claims Act Amendments, supra*, 99th Cong. 118, 159). The Tenth Circuit found the reference to the tolling section of the general statute of limitations, 28 U.S.C. § 2416(c), telling, as that section uses the phrase "an official of the United

States charged with the responsibility to act in the circumstances," as opposed to the term "Attorney General," when setting forth the tolling provision. *Id.* at 725. The Tenth Circuit found that section 3731(b)(2), like the tolling provision in the general statute of limitations, was meant to apply only to the government. *Id.* It also, like several other courts addressing this issue, found that the purposes underlying the FCA supported this interpretation. *Id.* at 725.

This court joins the Eastern and Western Districts of Texas in concluding that the six-year statute of limitations should apply to FCA claims that are brought by *qui tam* relators when the United States does not intervene. The court finds the reasoning in *Sikkenga* persuasive. Subsection 3731(b)(2) refers only to the United States, not *qui tam* relators, and the legislative history of the statute suggests that Congress desired to give the *government* more flexibility in prosecuting FCA violations. Moreover, as noted by the *Sikkenga* court, "Congress viewed qui tam prosecutions as providing a means to achieve *rapid* exposure to fraud against the public fisc, unencumbered by the lack of resources or the bureaucracy inherent in enforcement by public authorities." *Id.* Allowing relators to take advantage of a tolling statute that specifically mentions the government and does not refer to relators runs contrary to the purpose of allowing *qui tam* relators to proceed with the action in the first place.

None of the cases cited to the court in relation to whether to apply the tolling provision in state FCA claims in states that have FCA statutes of limitation that are substantially similar to the federal provision deals with state FCA claims. The parties have not provided briefing informing the court how each particular state would treat this issue and thus appear to agree that the interpretation

of the federal statute applies to the state statutes.[33] Of the states that Relators contend have limitations provisions parallel to the federal statute, the FCA limitations clauses of Georgia, Indiana, New Hampshire, New Jersey, Oklahoma, Rhode Island, and Michigan are all substantially similar to the federal FCA limitations clause. *Compare* 31 U.S.C. § 3731(b), *with* Ga. Code Ann. § 49-4-168.5; Ind. Code § 5-11-5.5-9(b); N.H. Rev. Stat. § 167:61-b(VII)(b); N.J. Stat. Ann. § 2A:32C-11; 63 Okla. St. Ann. § 5053.6; R.I. Gen. Laws Ann. 1956, § 9-1.1-5; Mich. Comp. Laws § 400.614 (West, Westlaw current through P.A. 2011, No. 142). The only state of these states still at issue is Michigan. The court finds that the six-year limitations period controls, and SPI's motion to dismiss the Michigan FCA claims relating to conduct occurring before July 16, 2002 is therefore GRANTED. The Michigan FCA claims relating to conduct occurring before July 16, 2002, are DISMISSED WITH PREJUDICE.

c. Colorado, Connecticut, Maryland, and North Carolina

SPI contends that the Colorado, Connecticut, Maryland, and North Carolina FCAs have six-year statutes of limitations and that all alleged violations of these statutes occurring before September 15, 2004, which is six years prior to the date the claims were added, should be dismissed. Relators do not present any specific arguments rebutting SPI's allegation that the statutes of limitation in these state FCAs partially bar their claims under the FCAs of those states. *See* Dkt. 131. The court, however, will examine the statutes of limitations periods in each of these states to determine if partial dismissal is appropriate.

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[33] The court notes, given the differing viewpoints with regard to the meaning of the federal statute, that the state legislatures that adopted this language could likewise have different views about its meaning. However, the only state at issue is Michigan, and the court has found no Michigan cases on point. It therefore looks to the federal courts' interpretation of the parallel federal statute for guidance.

i) Colorado. The Colorado FCA parallels the federal statute, to an extent. However, unlike the federal statute, which refers to the section that describes both government and *qui tam* claims generally, without specifying subsections, the Colorado statute specifies that "a civil action under section 25.5-4-306(1) or (2) may not be brought after the later of . . . ." Subsection (1) addresses the responsibilities of the Colorado Attorney General to investigate claims and bring civil actions; subsection (2) provides the right for a relator to bring a civil action on behalf of the relator and the state. Colo. Rev. Stat. Ann. § 25.5-4.306(1)-(2). Since the Colorado FCA, unlike the federal statute, specifies the subsections for both government and *qui tam* actions, it appears that the Colorado legislature meant for the ten-year tolling provision to apply to both types of actions. Colo. Rev. Stat. Ann. § 25.5-4-307(1).[34] Accordingly, SPI's motion to partially dismiss the Colorado claims under the statute of limitations is DENIED.

ii) Connecticut. The Connecticut FCA similarly specifies that a "civil action under section 17b-301c to 17b-301g, inclusive, may not be brought: (1) More than six years after the date on which the violation . . . is committed, or (2) more than three years after the date when facts material to the right of action are known or reasonably should have been known by the [state], but in no event more than ten years after the date on which the violation is committed, whichever last occurs." Conn. Gen. Stat. Ann. § 17b-301l. Section 17b-301c describes how the Connecticut Attorney General may investigate a violation and file a civil suit, and 17b-301d describes how a person may bring a *qui tam* action. *Id.* §§ 17b-301c, 17b-301d. Thus, it appears the Connecticut

[34] A review of the legislative history provided on the Colorado General Assembly's website reveals that the original version of the bill had a flat six-year statute of limitation; it is unclear when the Colorado General Assembly added the ten-year tolling provision. *See* 63rd Gen. Assembly, 1st Reg. Sess., H.B. 01-1040, http://www.leg.state.co.us/2001/inetcbill.nsf/fsbillcont/C4724570B687C76387256954005F5FAE?Open&file=1040ju_01.pdf.

legislature meant for the ten-year tolling provision to apply to both types of actions. Accordingly, SPI's motion to partially dismiss the Connecticut claims under the statute of limitations is DENIED.

iii) Maryland.[35] With regard to the Maryland statute, it is clear that a flat six-year statute of limitations does not always apply. Rather, a civil action under the Maryland FCA may not be filed after the later of "(1) 6 years after the date on which the underlying violation of § 2-602(a) of this subtitle occurred; or (2) 3 years after the date when facts material to the right of action are *known by the relator*, the State's Inspector General, or the Director of the State's Medicaid Fraud Control Unit or reasonably should have been known, but in no event more than 10 years after the date on which the underlying violation of § 2-602(a) of this subtitle is committed." Md. Code Health-Gen. Ann. § 2-609(a) (West, Westlaw through 2010 Reg. Sess.) (emphasis added). This version, unlike the federal version, specifically mentions the relator in the tolling provision. This shows that the Maryland General Assembly intended for both subsections to apply to both the government and *qui tam* relators. Since the Maryland claims were added on September 15, 2010, all violations occurring within six years—on or after September 15, 2004—are clearly within the statute of limitations. All violations occurring ten years or more before filing—before September 15, 2000—are clearly outside the statute and should be DISMISSED. Claims occurring between September 15, 2000 and September 15, 2004 are plausibly within the statute, as Relators may not have discovered them until September 15, 2007—three years before the Maryland claims were filed. As such, SPI's motion to dismiss as it relates to the alleged violations of the Maryland FCA occurring between September 15, 2000 and September 15, 2004 is DENIED. SPI's motion to

[35] In Part II.E.6, *infra*, the court dismisses all claims under the Maryland FCA with prejudice. It addresses the motion for partial dismissal under the statute of limitations as an alternate means of dismissal.

dismiss as it relates to alleged violations of the Maryland FCA occurring before September 15, 2000 is GRANTED and these claims, to the extent they exist, are DISMISSED WITH PREJUDICE.

iv) North Carolina.[36] The North Carolina statute appears to parallel the federal statute. *See* N.C. Gen. Stat. Ann. § 1-615 (West, Westlaw current through Ch. 18). The parties have provided no North Carolina cases interpreting its FCA, and the court has found none. Thus, it looks to the cases interpreting the parallel federal statute for guidance and will, accordingly, apply the six-year limitations period. SPI's motion to partially dismiss the North Carolina FCA claims that are allegedly barred by the statute of limitations is GRANTED. All alleged violations of the North Carolina FCA that occurred before September 15, 2004 are DISMISSED WITH PREJUDICE.

d. Texas

SPI moves to dismiss the Texas FCA claims occurring before June 10, 1999 because it alleges that Texas' four-year general statute of limitation applies, and the Texas claims were asserted in the original complaint on June 10, 2003. Dkt. 122. Relators argue that applying the Texas general statute of limitations "contradicts Texas' desire to be considered qualified to receive additional Medicaid funding under the Deficit Reduction Act ("DRA") by having provisions that are at least as effective as those in the federal FCA." Dkt. 131 at 40. SPI does not address this argument in its reply. However, the court finds nothing in the 4AC or Texas law that supports Relators' position that the normal statute of limitations should not apply. *See Foster*, 587 F. Supp. 2d at 817-18 (holding that the four-year limitations period in Texas Civil Practices and Remedies

[36] In Part II.E.6, *infra*, the court dismisses all claims under the North Carolina FCA with prejudice. It addresses the motion for partial dismissal under the statute of limitations as an alternate means of dismissal.

Code section 16.051 applied to the relator's *qui tam* FCA claims under the Texas Medicaid Fraud Prevention Act). Accordingly, SPI's partial motion to dismiss the claims under the Texas statute is GRANTED. Relators' claims for violations of the Texas statute that relate to alleged violations occurring before June 10, 1999 are DISMISSED WITH PREJUDICE.

e. Wisconsin

SPI moves to partially dismiss Relators' Wisconsin claims, asserting that Wisconsin has a 10-year statute of limitations and that, since Relators did not add the Wisconsin claims until November 10, 2009, all claims occurring before November 10, 1999 should be dismissed as time-barred. Dkt. 122. The Wisconsin FCA states that a "civil action may be brought based upon acts occurring prior to October 27, 2007, if the action is brought within the period specified in section 893.981. Wis. Stat. Ann. § 20.931 (West, Westlaw current through 2011 Act 31). Section 893.981 states, "An action or claim under s. 20.931 shall be commenced within 10 years after the action or claim accrues or be barred." *Id.* § 893.981. Thus, the alleged violations of the Wisconsin FCA occurring more than ten years before the Wisconsin FCA claims were filed are barred. SPI's motion to dismiss the claims based on alleged violations of the Wisconsin FCA occurring before November 10, 1999 is GRANTED, and these claims are DISMISSED WITH PREJUDICE.

6. Procedural Arguments (Counts 28-33)

SPI contends that counts 28-33 (asserting claims on behalf of Colorado, Connecticut, Maryland, Minnesota, North Carolina, and the City of Chicago) of the 4AC should be dismissed because Relators failed to serve the sealed complaint and a written disclosure of all material evidence on specific state officials as required by the state statutes under which the claims are filed. Dkt. 122 at 38. Additionally, SPI asserts that the court should dismiss the new claims because

Relators were granted leave to amend only to remedy pleading deficiencies, not to add new claims. *Id.* at 39. In the third amended complaint, Relators assert claims on behalf of six new states—Colorado, Connecticut, Maryland, Minnesota, North Carolina, and Chicago.

First, since the Chicago claims have been dismissed by agreement, the court need not address whether they should be dismissed on this procedural issue. Second, Solvay's assertion that Relators were given leave to amend solely to correct pleading deficiencies is not supported by the record. Relators motion to amend, which is contained within its response to a previous motion to dismiss, requests leave to amend "[i]f the Court concludes that Solvay Pharmaceuticals is entitled to either more specific pleading . . . or a more facially plausible claim," which certainly might lead one to suspect that they were only seeking leave to amend the current claims. However, Relators also state in their motion that "[t]hese *additions* and clarifications would not unduly prejudice Solvay Pharmaceutical at this early stage of litigation." Dkt. 102 at 67-68 (emphasis added). In the order granting the motion to amend, the court simply granted Relators' motion. Dkt. 104. While the better practice would have been to specifically move to add the new state claims, the court did not limit Relators to only clarifying existing claims. Relators could have filed a new complaint in each of these states rather than adding the new state claims into the instant complaint, and it is more efficient to the judicial system as a whole if the new claims (to the extent they are not being dismissed herein) and the old claims remain together.

With regard to the sealing argument, SPI and Relators both cite cases interpreting the federal FCA sealing provision and provide no guidance with regard to the laws of each individual state at issue. The text of the federal sealing provision and the sealing provisions of each of these FCAs is slightly different, but each requires the relator to file the complaint under seal, or "in camera," for

a time while the government considers whether to intervene. *See* Colo. Rev. Stat. Ann. § 25.5-4-306; N.C. Gen. Stat. Ann. § 1-608(b)(2) (2009); Conn. Gen. Stat. Ann. § 17b-301d(b); Md. Code Health-Gen. § 2-604(3); Minn. Stat. Ann. § 15C.05. None specifically advises whether a complaint filed by a relator that does not follow the technical provisions of the statute should be dismissed. Neither of the parties has provided any cases addressing these specific state statutes or legislative history of the individual state statutes, as opposed to the federal FCA, and the court has found none. Thus, the court turns to cases interpreting the federal sealing provision, which is similar to the sealing provisions at issue, for guidance with regard to the remedy when a relator fails to file a *qui tam* complaint under seal.

SPI cites *United States ex rel. Summers v. LHC Group, Inc.*, 623 F.3d 287, 298 (6th Cir. 2010) in support of its contention that the court should dismiss based on failure to file under seal and serve the sealed complaint. In *Summers*, a district court dismissed a *qui tam* action because the relator failed to initially file it under seal, as required by the FCA. *Summers*, 623 F.3d at 290. The Sixth Circuit, in reviewing the district court's judgment, discussed the legislative purpose behind the seal requirement, which was established in 1986: Requiring the complaint to be under seal "permit[s] the Government sufficient time in which it may ascertain the status quo and come to a decision as to whether it will intervene in the case filed by the relator." *Summers*, 623 F.3d at 292 (citations omitted). Additionally, the requirement "'prevent[s] alleged wrongdoers from being tipped off that they were under investigation.'" *Id.* (quoting *Erickson ex rel. United States v. Am. Inst. Biological Scis.*, 716 F. Supp. 908, 912 (E.D. Va. 1989)). The Sixth Circuit held "that violations of the procedural requirements imposed on *qui tam* plaintiffs under the False Claims Act preclude such plaintiffs from asserting *qui tam* status." *Id.* at 296. The Sixth Circuit reasoned that

(1) "Congress clearly identified a sixty-day *in camera* period was the correct length of time required" for the Government to consider whether it should intervene; and (2) Congress allowed for an extension of the sixty-day *in camera* period if the United States could show just cause, but failed to allow relators to shorten the period for just cause. *Id.* at 296-97.

Relators argue that the purpose of the *in camera* requirement has been met here even though they did not file the third amended complaint under seal because they "served the new states with all prior complaints and disclosure statements in a timely manner before filing the third amended complaint." Dkt. 131 at 41. Relators claim that "[v]irtually every other opinion addressing the issue has rejected [the] automatic dismissal" espoused by the *Summers* court. Dkt. 131 at 40. Relators rely, mainly, on *United States ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 245 (9th Cir. 1995),in which the Ninth Circuit expressly disagreed with the Sixth Circuit's holding in *Summers*.

In *Lujan*, a California district court dismissed a *qui tam* complaint because the *qui tam* relator disclosed the nature and existence of the action to the *Los Angeles Times* while the complaint was still under seal. 67 F.3d at 243. On appeal, the Ninth Circuit found that the plaintiff "clearly violated the seal provision" of the FCA. *Id.* at 244. However, rather than dismissing the claim outright as the court in *Summers* did, the Ninth Circuit considered whether dismissal was the "appropriate remedy for that violation." *Id.* at 244. The Ninth Circuit pointed out that "[n]o provision of the False Claims Act explicitly authorizes dismissal as a sanction for disclosures in violation of the seal requirement." *Id.* at 245. The Ninth Circuit then discussed whether the authorization for dismissal was implicit in the seal requirement. *Id.* The Ninth Circuit reasoned that the purpose of the seal was to strike a balance between two interests: (1) the overall purpose of allowing *qui tam* actions—"to encourage more private false claims litigation"; and (2) the purpose

of the sealing requirement—"to allow the Government an adequate opportunity to fully evaluate the private enforcement suit and determine both if that suit involves matters that Government is already investigating and whether it is in the Government's interest to intervene.'" *Id.* at 245 (quoting S. Rep. No. 345, 99th Cong., 2d Sess. 24, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5289). The seal requirement allows "the *qui tam* relator to start the judicial wheels in motion and protect his legislative rights, while allowing the government the opportunity to study and evaluate the relator's information for possible intervention or in relation to an overlapping criminal investigation." *Id.*

The Ninth Circuit, in formulating its rule, noted that the seal provision is not jurisdictional *Id.* at 245. The Ninth Circuit then instructed that the "district court must keep in mind *both* sides of the balance when constructing a sanction for a violation of the seal provision." *Id.* The Ninth Circuit provided several factors that district courts could consider before deciding if dismissal is warranted: (1) whether the government was harmed by the disclosure; (2) whether the violation of the sealing requirement was extreme or minor; and (3) whether the failure to seal was in bad faith. *Id.* at 245-47.

The Fifth Circuit has not yet reached this issue, and treatment by the district courts in the Fifth Circuit is scarce. Two federal district courts in Louisiana have addressed the issue, with differing results. A federal district court in the Eastern District of Louisiana addressed whether to dismiss a *qui tam* action for lack of subject matter jurisdiction when the relator filed his original complaint under seal but failed to file his first amended complaint under seal. *United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins.*, 668 F. Supp. 2d 780, 803 (E.D. La. 2009). The court held that the relator's failure to file the first amended complaint under seal "neither requires dismissal nor deprives [the] Court of jurisdiction," pointing out (1) that the FCA specifically says

"complaint" and does not refer to amendments when discussing the sealing requirement; (2) "numerous courts have held that [sealing] requirements are not jurisdictional and their violation does not require dismissal of the complaint." *Id.* (citing 31 U.S.C. § 3730(b)(2)). Another Eastern District of Louisiana court came to the opposite conclusion, albeit with little analysis.[37] *See Friedman v. F.D.I.C.*, No. 93-277, Civ. A. 93-415, 1995 WL 608462, at *3 (E.D. La. Oct. 16, 1995) (finding the requirement to file under seal, even for an amended complaint, to be a jurisdictional requirement and dismissing the case).

This court prefers the approach of the Ninth Circuit rather than the Sixth Circuit, as it allows for flexibility in cases in which the failure to seal causes no harm. However, in this case the outcome is the same with either standard. Here, Relators asserted *new* claims on behalf of Colorado, Maryland, North Carolina, Minnesota, and Connecticut when they filed their third amended complaint. The case was no longer under seal by the time Relators filed their third amended complaint, because the waiting period for the United States and all of the states on whose behalf the previous versions of the complaint had been filed had passed and no more extensions had been filed. The United States and each of the other states named in the original through the second amended complaint were given the opportunity to decide whether to intervene before the details of the complaint were made public. The new states were not afforded this same opportunity. Relators contend that they served the new states with all prior complaints and disclosure statement in a timely manner before filing the Third Amended Complaint. Dkt. 131 at 41. It is unclear whether they

[37] The *Branch* court cited a third Louisiana case in which it states the court granted summary judgment for failure to file the complaint under seal. *See Branch*, 668 F. Supp. 2d at 803 (citing *United States ex rel. Bain v. Ga. Gulf Corp.*, No. 01-562 (M.D. La. 2005)). There do not appear to be any orders commercially available in that case that grant summary judgment based on a sealing issue.

mean that they actually gave these states sixty days' notice or have some other interpretation of "timely manner," but the court does not consider such extrinsic evidence on a motion to dismiss. It is clear from the record that the complaint was no longer under seal when these new state claims were filed, and the new states deserved just as much opportunity as the states that were already included to consider any potential ongoing state investigations and decide if they wanted to intervene before the claims under the laws of each new state became public. While there is no evidence that the failure to seal the complaint under each of the state statutes at issue was in bad faith, the failure was not a minor technical glitch; instead, Relators appear to have completely disregarded the states' mandates, contained in each of their statutes, that complaints brought on their behalf be kept under seal until the states could review the issues. The court finds the equities weigh in favor of dismissal of these state claims. Accordingly, SPI's motion to dismiss the Colorado, Maryland, North Carolina, Minnesota, and Connecticut state FCA claims is GRANTED and the claims are DISMISSED WITH PREJUDICE.[38]

F. Count 34

In Count 34, Relators request that the court award them a percentage share of the damages from the "common fund" for states that do no allow relators to bring *qui tam* actions. Dkt. 114 at 247-48. Relators contend that the "Common Fund doctrine preserves the right of the litigant or counsel to an award from the Common Fund generated" so that states that do not have *qui tam*

[38] The court notes that under the Connecticut FCA, a *qui tam* relator may only bring a civil action "in the superior court for the judicial district of Hartford." Conn. Gen. Stat. Ann. § 17b-301d(b). Under the Maryland FCA, any claims must be brought "in a court of competent jurisdiction within the State." Md. Code Health-Gen. § 2-604(3). Since Solvay did not move to dismiss based on these sections and the court is dismissing the claims under both the Connecticut and Maryland statutes on other grounds, it will not address the impact of these sections.

statutes do not receive windfalls due to the efforts of the relator. *Id.* at 247. SPI moves for dismissal of count 34, arguing that it should be dismissed because (1) it is not a cause of action; and (2) the court lacks jurisdiction over non-*qui-tam* states. Dkt. 122 at 39. Additionally, Relators did not address SPI's argument in their initial response, and SPI therefore requests that the court dismiss the count as unopposed under Local Rule 7.4. Dkt. 139 at 25. Relators state, in their surreply, that there was no need to address the argument because Count 34 "is not a claim, but a request that any recovery from Solvay should be distributed a certain way among plaintiffs." Dkt. 140-1 at 1 n.2.

The court is not inclined to dismiss this "claim" at this stage in the litigation, under Rule 7.4 or for the other reasons asserted by Solvay. However, the court notes that it appears at this point that Relators will not be entitled to common fund relief from the non-*qui tam* states, as these states are not parties to this litigation.[39] For now, however, the motion to dismiss Count 34 is DENIED.

G. Prejudicial Dismissal/Motion to Amend

Finally, SPI argues that Relators' claims should be dismissed with prejudice because this case was filed in 2003 and Relators have "had five tries and are still unable to state a plausible cause of action." Dkt. 112 at 39. Relators assert that the complaint has only been substantively amended three times, as the current complaint merely redacted doctor names. Dkt 131 at 45.

Under Federal Rule of Civil Procedure 15(a), leave to amend must be "freely given when justice so requires." "Thus, unless there is a substantial reason to deny leave to amend, the discretion of the district court is not broad enough to permit denial." *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 (5th Cir. 1981). Substantial reasons include "undue delay, bad faith or

[39] Additionally, the court notes that, as Relators have acknowledged, the request for "common fund relief" is not really a cause of action and is therefore not accurately placed in the 4AC.

dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, and undue prejudice to the opposing party." *Id.*

In *United States ex rel. Dekort v. Integrated Coast Guard Sys.*, a case upon which SPI relies, the federal district court in the Northern District of Texas granted in part and denied in part a motion to dismiss the fifth amended complaint in a False Claims Act case. 705 F. Supp. 2d 519, 559 & n.18 (N.D. Tex. 2010). The claims the court dismissed were dismissed with prejudice. *Id.* The court noted that the relator had already "had the opportunity to amend his complaint five times, and in certain instances in response to arguments in support of dismissal by Defendants." *Id.* The court concluded that "further amendment would be futile." *Id.*

Here, Relators are on the fourth amended version of their complaint. However, the first and second amended versions were filed before the case was unsealed and defendants were served. *See* Dkts. 56-62 (return on service for various Solvay entities, all of which were served in January 2010); Dkt. 75 (order granting unopposed motion to unseal complaints and amended complaints). Defendants filed motions to dismiss the second amended complaint. Dkts. 94, 95. However, the court, rather than addressing the merits of defendants' arguments, granted Relators' alternative motion for leave to amend and denied the motions to dismiss as moot. Dkt. 104. Many of the issues involved in this case, as it relates to SPI's motion, are complex and in some instances unsettled, and the court therefore finds that dismissal of these more complex claims before Relators understand how this court would interpret the pleading requirements inappropriate given the liberal nature of Rule 15(a).

That being said, some of the issues raised in Solvay's motion are straightforward, and no amendment could cure the deficiencies. The claims that the court dismisses with prejudice are so dismissed because amendment would be futile.

III. ANALYSIS: SAI AND SNA'S MOTION TO DISMISS

SAI and SNA move to dismiss Relators' 4AC because it does not state with particularity the roles of SAI and SNA in the alleged misconduct as required by Federal Rule of Civil Procedure 9(b), fails to allege any facts showing that SNA and SAI engaged in any misconduct, and does not allege that they exhibited the total control and domination of SPI that would be required for Relators to state a claim against SAI and SNA based on the alleged misconduct of another corporate entity. Dkt. 121 at 3-4. SAI and SNA additionally assert that Relators' claims against them should be dismissed for all the reasons asserted in SPI's motion to dismiss. *Id.* at 20.

Relators argue first that issues regarding parent-subsidiary relationships are fact-specific inquiries and are inappropriate for resolution on a motion to dismiss. Dkt. 123. However, they also assert that they have pled that SPI was the alter ego of SAI and SNA with particularity, that the prohibition on group pleading should not apply in this case, and that, regardless, the court should not dismiss the alter ego claims without first providing Relators with the opportunity to conduct discovery on the issue. *Id.* Finally, Relators argue that the court should deny all of the grounds for dismissal raised in SPI's motion for the reasons asserted in their response to that motion.

First, as noted in Part II, *supra*, the court has granted SPI's motion to dismiss, in part. As further detailed in the Part IV, *infra*, the claims that the court dismisses with respect to SPI are also DISMISSED with regard to SAI and SNA. The court now turns to the substance of SAI and SNA's motion.

In the Fifth Circuit, a complaint containing "general allegations, which do[es] not state with particularity what representations each defendant made" does not meet the Rule 9(b) particularity requirement. *Unimobil 84, Inc. v. Spurney*, 797 F.2d 214, 217 (5th Cir. 1986). In order to state a claim under Rule 9(b), plaintiffs generally must plead the *who*, what, where, when, and how of the alleged fraud. *Tchuruk*, 291 F.3d at 350. General allegations that "defendants" engaged in fraudulent activity skips the first requirement—"who."

The *Grubbs* court specifically instructed that Rule 9(b) is context specific, and the court therefore considers the specific facts of this case when determining whether Relators have sufficiently pled the "who." First, since Relators have pled a nationwide fraudulent scheme rather than specific individualized fraudulent statements, it is not necessary to link each corporate entity to each individual aspect of the scheme. However, the complaint must plausibly link each corporate entity to the scheme or schemes alleged—in this case, off-label promotion, kickbacks, and ICD-9 code manipulation. Second, even if the complaint does not plausibly link each corporate entity to the scheme or schemes alleged, it may still satisfy the "who" aspect of the Rule 9(b) particularity requirement by plausibly alleging an alter ego relationship.

A. Are SAI and SNA Linked to the Fraudulent Scheme?

The allegations with regard to the involvement of the individual corporate defendants in the alleged scheme is scarce. Relators point out two instances in their response that arguably link SAI and SNA to the fraudulent scheme—SAI's involvement in auditing of sales representatives' expenses, which Relators suggest "goes to the heart of controlling how [SPI] marketed its drugs, and to the heart of the case," and Solvay S.A.'s press release related to the Columbine tragedy, which Relators contend shows how all of the Solvay companies were run centrally by Solvay S.A. Dkt.

123 at 21. Any potential link between these alleged facts and the national marketing scheme to get physicians to prescribe Luvox, AndroGel, and Aceon to patients on federal healthcare programs is extremely weak and not sufficient to state a claim under Rule 9(b) against these individual corporate entities.

B. Are the Alter Ego Allegations Plausible?

Relators argue, however, that this link is not necessary because SPI's actions can be imputed to SAI and SNA, as SPI is SNA and SAI's alter ego. Dkt. 123 at 11-16. SAI and SNA contend, however, that the 4AC does support Relators' alter ego theory. Dkt. 121 at 13. First, SPI claims that "the concept of piercing the corporate veil does not work across corporate family trees where sister corporations lack control over each other," and, while the 4AC alleges that SAI was SPI's parent company until 2004, it does not allege such a relationship between SNA and SPI. *Id.* And, as for SAI, SPI asserts that the 4AC does not adequately allege the alter ego factors. *Id.* at 13-14.

The Fifth Circuit has developed the following "laundry list of factors" for courts to use when determining whether a subsidiary is the alter ego of its parent for the purpose of piercing the corporate veil:

> (1) the parent and the subsidiary have common stock ownership;
> (2) the parent and the subsidiary have common directors or officers;
> (3) the parent and the subsidiary have common business departments;
> (4) the parent and subsidiary file consolidated financial statements and tax returns;
> (5) the parent finances the subsidiary;
> (6) the parent caused the incorporation of the subsidiary;
> (7) the subsidiary operates with grossly inadequate capital;
> (8) the parent pays the salaries and other expenses of the subsidiaries;
> (9) the subsidiary receives no business except that given to it by the parent;
> (10) the parent uses the subsidiary's property as its own;
> (11) the daily operations of the two corporations are not kept separate; and
> (12) the subsidiary does not observe the basic corporate formalities, such as keeping separate books and records and holding shareholder and board meetings.

United States v. Jon-T Chems., Inc., 768 F.2d 686, 691-92 (5th Cir. 1985). SAI and SNA and Relators agree, to the extent a veil piercing theory is available, that the court should apply the *Jon-T Chemicals* factors to determine if Relators have plausibly pled that SAI and SNA can be liable as alter egos of SPI for SPI's alleged violations of the federal FCA. SAI and SNA contend, however, that (1) these factors cannot be applied to SNA, which is a sister corporation, not a parent; and (2) regardless, Relators failed to allege these factors. Relators contend first that whether there is an alter-ego relationship is a question of fact that is inappropriate to resolve at the motion to dismiss stage. Relators also claim that sibling corporations, as well as subsidiaries, can be alter egos, and that they have pled enough facts supporting the *Jon-T Chemicals* factors to survive a motion to dismiss for both SAI and SNA. They additionally assert that, even if they have not, they should be allowed conduct discovery on the alter ego issue before being subjected to dismissal.

1. Alter Ego Allegations

The majority of the 4AC refers to all Solvay defendants collectively as "Solvay." However, before discussing jurisdiction and venue, the 4AC contains discussion of the relationship among the various Solvay defendants and the individual Solvay defendants' roles within the larger corporation. *See* Dkt. 114 at 8-10. According to Relators, Solvay SA is a "large multinational group of companies that engage or have engaged in a variety of business activities, including developing, marketing, and selling pharmaceutical products" that is incorporated in Belgium. Dkt. 114 at 3-4. SAI, which is a holding company for the North American subsidiaries of Solvay S.A., is a wholly owned subsidiary of Solvay S.A. Dkt. 114 at 6; Dkt. 121 at 2. Relators also allege that SPI was a wholly-owned subsidiary of SAI from 1986 until late 2004. *Id.* at 6-7. SNA, which Relators contend oversees and coordinates the activities of Solvay S.A.'s business in the United States, is a

wholly owned subsidiary of SAI. Dkt. 114 at 6; Dkt. 121 at 2. Relators claims that SNA "provides financial, legal, lobbying, recruiting, compliance and other services to Solvay S.A.'s businesses in North America." *Id.*

Relators contend that SPI is the alter ego of SNA, SAI, Solvay Pharmaceuticals SARL and Solvay S.A. because without SPI these other defendants would have been forced to perform SPI's services for themselves. *Id.* at 7. Relators contend that these entities have common officers and directors, that Solvay S.A.'s executives regularly visit the American subsidiaries, and that Solvay S.A. and SAI have exerted supervision, control, and dominion over SPI's activities, decisions, policies, and practices relating to development, human resources, legal issues, budget, accounting, employee compensation, employee benefits, employee expenses, manufacturing, and public relations. *Id.* at 8.

Relators contend that various aspects of Solvay's business are centralized in Belgium. For instance, each Solvay subsidiary allegedly submits its annual budget to Solvay S.A, and all Solvay affiliates submit financial data through a database in Belgium so that is can be grouped and placed in a consolidated global annual report. *Id.* at 7. All affiliates accessed research and development and manufacturing policies through a centralized database. *Id.* SPI allegedly wrote the global policies relating to research and manufacturing for the entire Solvay Group. *Id.*

Relators allege that SPI employees had to obtain approval for airline chartering, purchases for club memberships, and season tickets from SAI. *Id.* at 9. Additionally, the procedure for milage reimbursement for SPI was set by SAI, and SAI allegedly provided insurance coverage to SPI until at least 2002. *Id.* Relators additionally allege that the funds for health coverage for all Solvay companies was combined and comingled in a Welfare Benefits Plan that provided health care

coverage to all those employed by SAI, including those who worked for SPI, and that SAI provided the savings and pension plans offered to SPI employees. *Id.* Relators also contend that SPI communicated with SAI and Solvay S.A. on business issues, including marketing campaigns for drugs and other business strategies. *Id.* Relators provide the following example: an executive at SAI allegedly sent a memorandum to executives at SPI describing an audit of the expenses of twenty sales representatives in the Southwest Region. *Id.* at 9-10 & Exh. 1. The memorandum described the expenses as "questionable. *Id.* at 10 & Exh. 1. Relators also point out that Solvay S.A. and SAI often appeared on press releases with SPI. *Id.* at 10. They specifically reference the press release following the Columbine tragedy, which was published and copyrighted by Solvay S.A. *Id.* Relators contend that this shows that "Solvay S.A. takes or took an active role in addressing liability issues that may arise from drugs made by its subsidiaries." *Id.*

2. Are the Allegations Sufficient with Regard to SNA?

The 4AC alleges that SPI and SNA are both wholly owned subsidiaries of SAI and are thus sister corporations. Under the plain language of the text of the *Jon-T Chemicals* test, the test applies to *parents* and *subsidiaries*, not sister companies. However, some courts have applied the alter ego doctrine to sister companies. *See, e.g.*, *Dickson Marine Inc. v. Panalpina, Inc.*, 179 F.3d 331, 338-39 (5th Cir. 1999) (applying an alter ego analysis under *Hargrave v. Fibreboard Corp.*, 710 F.2d 1154 (5th Cir. 1983) to determine if the contacts of a sibling corporation could be attributed to its sibling for the purpose of establishing minimum contacts, and indicating that since the companies were siblings, rather than parent-subsidiary, a "stronger showing" may be necessary); *Nichols v. Pabtex, Inc.*, 151 F. Supp. 2d 772, 780 (E.D. Tex. 2001) (noting that courts that have addressed the distinction between parent-subsidiary and sister-sister in alter ego cases "indicate that the distinction

. . . is not relevant" and collecting cases). The court, in accordance with these cases, agrees with Relators that, in certain circumstances, sister corporations could be alter egos.

Here, however, the 4AC simply does not contain enough allegations about SNA's relationship to SPI or the alleged fraudulent scheme to plausibly state a claim against SNA on an alter ego theory. The only facts alleged supporting Relators' contention that SPI is SNA's alter ego are (1) SNA provides various services for all Solvay S.A. businesses in North America, which includes SPI; (2) the Chief Executive Officer of SAI served on the boards of both SNA and SPI; (3) all Solvay affiliates had access to the database containing research and development and manufacturing policies and research findings, including some policies written by SPI; and (4) all Solvay affiliates submit financial data to a database in Belgium and that data is grouped in a global annual report. Dkt. 123 at 15-16. These allegations, if taken as true, do not indicate that SNA "totally dominate[d] and control[led] [SPI], operating [SPI] as its own agent or conduit." *Jon-T Chems.*, 768 F.2d at 691. At most, these allegations provide minimal support for three of the *Jon-T Chemicals* factors. "[T]he alter ego question depends on the totality of the facts," and these alleged facts are not sufficient. *Id.* at 692. Here, there are no alleged facts that, "if proved, would even arguably permit a court to impose liability on [SNA] for the acts of [SPI] under an alter ego theory." *Resolution Trust Corp. V. Driscoll*, 984 F.2d 44, 48 (1st Cir. 1993). SNA and SAI's motion for summary judgment with regard to claims asserted against SNA is GRANTED.

3. Are the Alter Ego Allegations Sufficient with Regard to SAI?

The 4AC alleges that SAI is SPI's parent corporation, and there are significantly more allegations that support the *Jon-T Chemicals* factors for SAI. SPI was allegedly a wholly-owned subsidiary of SAI until 2005, the CEO of SAI and the Vice President of Finance for SAI also served

on SPI's Board of Directors, SAI provides insurance coverage and is in charge of the savings and pension plans for SPI employees, all Solvay affiliates' financial data is grouped in a global annual report, SAI paid part of the purchase price for SPI, SAI sets mileage reimbursement for SPI employees, SAI approves airline chartering and purchase of any club memberships and season tickets for SPI, SAI sent an audit memoradum to SPI questioning reimbursement requests for alleged kickbacks, and SAI and SPI appeared on press releases together relating to SPI drugs. These allegations are sufficient, if taken as true, to plausibly allege that SPI is the alter ego of SAI. Thus, SAI's motion to dismiss based on the lack of specific allegations against SAI is DENIED because Relators have plausibly alleged that SPI is SAI's alter ego.

4. Alter Ego Liability for State FCA Claims

SAI and SNA assert that Georgia law applies to the state law claims because Georgia is SPI's state of incorporation, and Relators do not disagree with this contention. Dkts. 121, 123. SAI and SNA contend that the Georgia standard is similar to the *Jon-T Chemicals* standard except that Georgia law also requires insolvency as a prerequisite for piercing the corporate veil. Dkt. 121 at 15 n.4. SAI and SNA argue that Relators have not pled that SPI is insolvent and thus request dismissal of all the state law claims against SAI and SNA. *Id.* Relators argue that insolvency is only one factor Georgia courts consider when deciding whether to pierce the corporate veil. Dkt. 135-1 at 5.

Courts should exercise "great caution" when disregarding the legal entity of a corporation. *Amason v. Whitehead*, 367 S.E.2d 107, 107 (Ga. Ct. App. 1988). "There must be evidence of abuse of the corporate form," and the "plaintiff must show that the defendant 'disregarded the separateness of legal entities by commingling on an interchangeable or joint basis or confusing the otherwise

separate properties, records or controls.'" *Id.* (quoting *Earnest v. Merck*, 358 S.E.2d 661 (Ga. App. 1987)). "'To establish the alter ego doctrine it must be shown that the stockholders' disregard of the corporate entity made it a mere instrumentality for the transaction of their own affairs; that there is such unity of interest and ownership that the separate personalities of the corporation and the owners no longer exist; and to adhere to the doctrine of corporate entity would promote injustice or protect fraud.'" *Farmers Warehouse of Pelham, Inc. v. Collins*, 137 S.E.2d 619, 625 (Ga. 1964) (quoting Fletcher Cyclopedia Corporations, vol. 1, § 41.1, p. 169).

SAI and SNA argue that under Georgia law the alleged alter ego must be insolvent for a court to pierce the corporate veil. Dkt. 128. They cite *In re Friendman's Inc.*, in support of this contention. *Friendman's*, 385 B.R. 381, 415 (S.D. Ga.), *rev'd on other grounds*, 394 B.R. 623 (S.D. Ga. 2008). In *Friendman*, the plaintiff, like Relators, argued that insolvency is only one factor to consider when deciding to pierce the corporate veil. *Id.* The Bankruptcy Court in the Southern District of Georgia disagreed, citing to a 1985 Georgia Supreme Court case, *Johnson v. Lipton*, in which the Georgia Supreme Court unequivocally stated that insolvency was required to pierce the corporate veil. *Id.* (citing *Johson v. Lipton*, 328 S.E.2d 533 (Ga. 1985)). In *Johnson*, the Georgia Supreme Court considered a case in which an ex-employee of a corporation was attempting to pierce the corporate veil in order to hold a corporation's officers and shareholders liable for bonuses that were never paid. *Johnson*, 328 S.E.2d at 535. The Georgia Supreme Court, in reviewing a partial summary judgment granted in the defendants' favor by the trial court**,** noted that "as a precondition to a plaintiff's piercing the corporate veil and holding individual shareholders liable on a corporate claim, . . . there [must] be insolvency on the part of the corporation in the sense that there are insufficient corporate assets to satisfy the plaintiff's claim." *Id.* at 535.

Relators argue that other courts in Georgia have not specifically required insolvency and have, instead, relied on a laundry list like the *Jon-T* Chemicals court. Dkt. 135-1 at 5. Relators rely on *Amason*, *Ellis v. Edwards*, and *Earnest v. Merck*. *Id.* The *Amason* court did not specifically outline insolvency as a requirement for piercing the corporate veil, but it did cite *Johnson* after noting that there was no allegation on insolvency by the *Amason* plaintiff. *Amason*, 367 S.E.2d at 109. The *Ellis* court affirmed a district court's order granting summary judgment in favor of the individuals that the plaintiff alleged were individually liable for the debt of convenience stores they owned. *Ellis v. Edwards*, 348 S.E.2d 764, 764 (Ga. App. 1986). The appellate court, with little analysis, held that the "appellant ha[d] shown no evidence of abuse of the corporate form for the purpose of promoting fraud or injustice or evasion of tort or contractual responsibility." *Id.* While there is no mention of insolvency, the absence of the term is hardly telling given that the entire opinion is only two paragraphs long. In *Earnest*, the Georgia appellate court held that the plaintiff had "not raised a material issue that in essence John Merck was nothing more than the alter ego of the two co-defendant corporations or that Merck made the corporate assets vehicles for his own private affairs or that there was such a unity of interest and ownership that separate personalities of the corporation and owner did not exist." *Earnest*, 358 S.E.2d at 664. The court did not offer every factor it considered in making this determination, and there is no indication whether the court considered insolvency or not. *See id.* It certainly could have required a showing of insolvency as required by *Johnson* before reaching the conclusions it reached. The court will not rely on the absence of an express indication of how insolvency played into these courts' analyses to determine if insolvency was merely a factor or not considered at all.

The court, in applying Georgia law, is bound by the Georgia Supreme Court's requirement in *Johnson* that insolvency is a precondition to piercing the corporate veil. As such, since Relators, SNA, and SAI all agree that Georgia corporate law should apply to the alter ego allegations for the state FCA claims and there are no specific allegations of insolvency with regard to SNA or SAI in the counts asserting state FCA claims, SNA and SAI's motion to dismiss the state FCA claims is GRANTED, and the state FCA claims asserted against SNA and SAI are DISMISSED.

C. Request for Prejudicial Dismissal vs. Request for More Discovery

SAI and SNA move for prejudicial dismissal for the same reasons SPI asserted that the claims against SPI should be dismissed with prejudice. Relators argue that the court should not dismiss the claims against SNA and SPI without first allowing them the opportunity to conduct discovery on the relationships between SNA, SAI, and SPI. Dkt. 123 at 22. Relators claim that depositions of the corporate representatives would help it further investigate the facts. *Id.* SNA and SPI assert that Relators cannot use discovery to try to backfill insufficiently pled FCA claims. Dkt. 128 at 12.

Relators point out that courts often provide parties with time to conduct discovery on the alter ego issue in lieu of dismissal. In some cases it is appropriate to allow more time to conduct discovery before dismissing alter ego claims. However, as the Fifth Circuit has noted, in the FCA context, a well-pled complaint is a *qui tam* plaintiff's "ticket to the federal discovery apparatus." *Grubbs*, 565 F.3d at 185 n.10, 190 (citing *Russell*, 193 F.3d at 308). Here, there is no complex issue of law with regard to what is needed to state an alter ego claim, and Relators have had ample opportunity to plead according to well-established precedent. Relators have failed to meet the pleading requirements and therefore do not get a ticket to discovery. SNA's motion to dismiss the

federal FCA claims against it is GRANTED, and these claims are DISMISSED WITH PREJUDICE. SAI and SNA's motion to dismiss the state FCA claims asserted against them is GRANTED, and these claims are DISMISSED WITH PREJUDICE.

IV. LEAVE TO AMEND

District courts should "'freely give leave" to amend when "justice so requires." Fed. R. Civ. P. 15(a)(2). "Denial of leave to amend may be warranted for undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies, undue prejudice to the opposing party, or futility of a proposed amendment." *Steury*, 625 F.3d at 270. Here, the court finds that amendment of the claims that have been dismissed or partially dismissed with prejudice would be futile. However, the court believes that justice requires that it provide Relators with an opportunity to re-plead the claims that it has dismissed without prejudice and *only* those claims. No additional claims shall be added. Accordingly, the court GRANTS leave to amend.[40]

V. CONCLUSION

A. SNA and SAI's Motion

SNA and SAI's motion to dismiss the federal FCA claims asserted against SAI because there are insufficient allegations that SPI is SAI's alter ego and there are no specific allegations of misconduct by SAI is DENIED.

SNA and SAI's motion to dismiss claims the federal FCA claims asserted against SNA because there are insufficient allegations that SPI is SNA's alter ego and there are no specific allegations of misconduct by SNA is GRANTED. All federal FCA claims asserted against SNA are DISMISSED WITH PREJUDICE.

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[40] The court notes, however, that it likely will not be inclined to grant leave to amend again.

SNA and SAI's motion to dismiss the state FCA claims asserted against them is GRANTED. The state FCA claims asserted against SNA and SAI are DISMISSED WITH PREJUDICE.

There are no remaining claims against SNA. The only remaining claims against SAI are the federal FCA claims. SNA and SPI expressly adopted the arguments in SPI's motion to dismiss, though, so, as noted below, some of the federal FCA claims asserted against SAI are also dismissed.

B. SPI's Motion

SAI and SNA specifically adopted the arguments in SPI's motion to dismiss, so the court refers to SPI's motion and SAI and SNA's motion collectively as "Solvay's motions." Solvay's motions to dismiss Count 1 and Count 2 for failure to plead with particularity under Rule 9(b) are DENIED with respect to Relators' claims relating to off-label promotion, DENIED with respect to Relators' kickback claims for AndroGel and Aceon, GRANTED with respect to Relators' kickback claim for Luvox, and GRANTED with respect to Relators' claims relating to ICD-9 code manipulation. Relators' kickback claims relating to Luvox are DISMISSED WITHOUT PREJUDICE. Relators' ICD-9 code manipulation claims are DISMISSED WITHOUT PREJUDICE.

Solvay's motions to dismiss Relators' kickback claims under Rule 12(b)(6) because Relators fail to assert that the parties submitting the claims certified compliance with the AKS are GRANTED and Relators' kickback claims are DISMISSED WITHOUT PREJUDICE.[41] Solvay's motions to dismiss Relators' off-label promotion claims under Rule 12(b)(6) for failure to plead falsity or materiality are DENIED. Solvay's motions to dismiss Relators' ICD-9 code manipulation

[41] Since the court dismissed the kickback claims relating to Luvox for failure to plead with particularity, the 12(b)(6) dismissal for failure to plead certification, with regard to Luvox, is an alternative means of dismissal.

claims under Rule 12(b)(6) for failure to plead falsity or materiality are DENIED AS MOOT, as the court has already dismissed the ICD-9 code manipulation claims for failure to plead with particularity.

Solvay's motions to dismiss Count III (conspiracy claim) are GRANTED. Count III is DISMISSED WITHOUT PREJUDICE. Solvay's motions to dismiss Count IV (retaliation claim) are also GRANTED. Count IV is DISMISSED WITHOUT PREJUDICE.

Solvay's motions to partially dismiss Count VIII (Massachusetts Claims Act) are GRANTED. All claims relating to alleged violations of the Massachusetts Claims Act occurring before July 1, 2000, are DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count X (Delaware False Claims and Reporting Act) because Delaware allegedly did not provide a substantial evidence statement are DENIED. Solvay's motions to partially dismiss Count X based on alleged fraud before the Delaware False Claims and Reporting Act was enacted are GRANTED. Relators' claims relating to alleged violations of the Delaware False Claims and Reporting Act occurring before July 30, 2000 are DISMISSED WITH PREJUDICE.

Solvay's motion to partially dismiss Count XII (Hawaii FCA) are GRANTED. Relators' claims relating to alleged violations of the Hawaii FCA occurring before May 26, 2000 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XV (Virginia Fraud Against the Taxpayer Act) are GRANTED. Relators' claims relating to alleged violations of the Virginia Fraud Against the Taxpayer Act occurring before January 1, 2003 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XVI (Georgia State False Medicaid Claims Act) are GRANTED. Relators' claims relating to alleged violations of the Georgia State False Medicaid Claims Act occurring before May 24, 2007 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XVII (Indiana False Claims and Whistleblower Protection Act) are GRANTED. Relators' claims relating to alleged violations of the Indiana False Claims and Whistleblower Protection Act occurring before July 1, 2005 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XVIII (Michigan Medicaid FCA) are GRANTED. Relators' claims relating to alleged violations of the Michigan Medicaid FCA occurring before July 16, 2002 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XIX (Montana FCA) are GRANTED. Relators' claims relating to alleged violations of the Montana FCA occurring before October 1, 2005 are DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count XX (New Hampshire FCA) because Relators allegedly cannot litigate the claims are DENIED. However, Solvay's motions to partially dismiss the New Hampshire FCA claims as they relate to fraud occurring before the statute was enacted are GRANTED. Relators' claims relating to alleged violations of the New Hampshire FCA occurring before January 1, 2005 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XXI (New Jersey FCA) are GRANTED. Relators' claims relating to alleged violations of the New Jersey FCA occurring before March 13, 2008 are DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count XXII (New Mexico Medicaid FCA) because Relators have not alleged that New Mexico provided a substantial evidence letter are DENIED. However, Solvay's motions to dismiss the New Mexico Medicaid FCA portion of Count XXII because Relators are not "affected persons" under the statute are GRANTED. Relators' claims under the New Mexico Medicaid FCA are DISMISSED WITH PREJUDICE. Additionally, Solvay's motions to partially dismiss Relators' claims under the New Mexico Fraud Against Taxpayers Act are GRANTED. All claims under this act relating to claims, records or statement, or conspiracies occurring before July 1, 2007 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XXIII (New York FCA) are GRANTED. Relators' claims relating to alleged violations of the New York FCA occurring before January 1, 2007 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XXIV (Oklahoma Medicaid FCA) are GRANTED. Relators' claims relating to alleged violations of the Oklahoma Medicaid FCA occurring before January 1, 2007 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XXV (Rhode Island FCA) are GRANTED. Relators' claims relating to alleged violation of the Rhode Island FCA occurring before July 1, 2007 are DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count XXVI (Texas FCA) because Relators cannot litigate on behalf of Texas are DENIED. However, Solvay's motions to partially dismiss Count XXVI under the Texas FCA statute of limitations are GRANTED. Relators' claims for alleged violations of the Texas FCA occurring before June 10, 1999 are DISMISSED WITH PREJUDICE.

Solvay's motions to partially dismiss Count XXVII (Wisconsin FCA) are GRANTED. Relators' claims for alleged violations of the Wisconsin FCA occurring before November 10, 1999 are DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count XXVII (Colorado FCA) for failure to seal the complaint are GRANTED and the claims based on the Colorado FCA are DISMISSED WITH PREJUDICE. Solvay's motions to partially dismiss Count XXVII based on the statute of limitations and the date of enactment are DENIED.

Solvay's motions to dismiss Count XXIX (Connecticut FCA) for failure to file under seal are GRANTED. Count XXIX is therefore DISMISSED WITH PREJUDICE. Moreover, even if it were inappropriate to dismiss these claims based on the failure to seal, the claims for violations of the statute occurring before it was enacted would not be valid. Thus, alternatively, the claims under the Connecticut FCA relating to violations occurring before October 5, 2009 are DISMISSED WITH PREJUDICE. Solvay's motions to dismiss Count XXIX due to limitations are DENIED.

Solvay's motions to dismiss Count XXX (Maryland FCA) because Relators failed to seal the complaint are GRANTED as are Solvay's motions to dismiss Count XXX because the court was required to dismiss the complaint as soon as Maryland declined to intervene. Count XXX is therefore DISMISSED WITH PREJUDICE. Moreover, even if it were inappropriate to dismiss the Maryland claims based on the failure to seal the complaint, the claims would be partially barred under the Maryland FCA statute of limitations. Thus, alternatively, all claims relating to alleged violations of the Maryland FCA occurring before September 15, 2000 are DISMISSED WITH PREJUDICE as time-barred.

Solvay's motions to dismiss Count XXXI (Minnesota FCA) because Relators failed to file the claim under seal are GRANTED. Count XXXI is DISMISSED WITH PREJUDICE. Moreover, even if dismissal for failure to seal were not appropriate, Count XXXI would be partially dismissed because some of the claims arose before the statute was enacted. Thus, alternatively, Relators' claims relating to alleged violations of the Minnesota FCA occurring before July 1, 2010 are DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count XXXII (North Carolina FCA) because Relators failed to file the claim under seal are GRANTED. Count XXXII is DISMISSED WITH PREJUDICE. Moreover, even if dismissal for failure to seal were not appropriate, Count XXXII would be partially dismissed because some of the claims would be barred by the statute of limitations. Thus, alternatively, Relators' claims relating to alleged violations of the North Carolina FCA occurring before September 16, 2004 are DISMISSED WITH PREJUDICE.

Relators do not contest dismissal of the Count XXXIII. Therefore, Solvay's motions to dismiss Count XXXIII (City of Chicago) are GRANTED, and Count XXXIII is DISMISSED WITH PREJUDICE.

Solvay's motions to dismiss Count XXXIV are DENIED.

C. Leave to Amend

The court hereby GRANTS leave to amend the 4AC to remedy the inadequacies identified herein. Relators *may not* add new claims.

Signed at Houston, Texas on October 12, 2011.

Gray H. Miller
United States District Judge